IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BECTON, DICKINSON AND COMPANY, GENEOHM SCIENCES CANADA, INC. and HANDYLAB, INC.,	)	
Plaintiffs,	)	C.A. No. 19-1126 (LPS)
v.	)	**DEMAND FOR JURY TRIAL**
NEUMODX MOLECULAR, INC., QIAGEN N.V., QIAGEN GMBH, QIAGEN NORTH AMERICAN HOLDINGS, INC., and QIAGEN LLC,	)	
Defendants.	)	

SECOND AMENDED AND SUPPLEMENTAL COMPLAINT

Becton, Dickinson and Company, GeneOhm Sciences Canada, Inc. (collectively "BD"), and HandyLab, Inc. ("HandyLab" and collectively with BD, "Plaintiffs"), by and through their attorneys, file this Second Amended and Supplemental Complaint against NeuMoDx Molecular, Inc. ("NeuMoDx") and QIAGEN N.V., QIAGEN GmbH, QIAGEN North American Holdings, Inc., and QIAGEN LLC (collectively "QIAGEN" and together with NeuMoDx, "Defendants"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the United States Patent Act, 35 U.S.C. §§ 1 *et seq.*, including 35 U.S.C. § 271.

2. Plaintiffs bring this action to seek relief for Defendants' infringement of Plaintiffs' rights arising under the Patent Laws of the United States 35 U.S.C. § 1, *et seq.*, from U.S. Patent Nos. 8,273,308; 8,703,069; 7,998,708; 8,323,900; 8,415,103; 8,709,787; 10,494,663; 10,364,456; 10,443,088; 10,604,788; 10,625,261; 10,625,262; and 10,632,466 (collectively "the Asserted Patents").

THE PARTIES

3. HandyLab, a wholly owned subsidiary of Becton, Dickinson and Company, is a corporation organized and existing under the laws of Delaware. HandyLab's officers and directors control, direct, and coordinate the corporation's activities from Franklin Lakes, NJ. HandyLab is the current owner by assignment of the Asserted Patents.

4. Becton, Dickinson and Company is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 1 Becton Drive, Franklin Lakes, NJ 07417. GeneOhm Sciences Canada, Inc., a wholly owned subsidiary of Becton, Dickinson and Company, is a corporation organized and existing under the laws of Canada, with its principal place of business at 2555 Boul du Parc-Technologique Québec G1P4S5 Canada. BD is the exclusive licensee of the Asserted Patents, specifically Becton, Dickinson and Company has an exclusive license for analyzers practicing the Asserted Patents, and GeneOhm Sciences Canada, Inc. has an exclusive license for assays and consumables practicing the Asserted Patents.

5. Upon information and belief, NeuMoDx is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1250 Eisenhower Place, Ann Arbor, Michigan 48108-3281. Upon information and belief, NeuMoDx was acquired by QIAGEN North American Holdings, Inc. ("QIAGEN NA") on September 17, 2020. Upon information and belief, NeuMoDx is a wholly owned subsidiary of QIAGEN NA and, ultimately, QIAGEN N.V.

6. Upon information and belief, QIAGEN N.V. is a corporation organized and existing under the laws of the Netherlands, with its principal place of business at Hulsterweg 82, 5912 PL Venlo, The Netherlands. Upon information and belief, QIAGEN N.V. is the ultimate corporate parent of the QIAGEN family, including NeuMoDx.

7. Upon information and belief, QIAGEN GmbH is a corporation organized and existing under the laws of Germany, with its principal place of business at QIAGEN Strasse 1, 40724 Hilden, Germany. Upon information and belief, QIAGEN GmbH is a wholly owned subsidiary of QIAGEN N.V.

8. Upon information and belief, QIAGEN North American Holdings, Inc. ("QIAGEN NA") is a corporation organized and existing under the laws of California, with its principal place of business at 19300 Germantown Road, Germantown, Maryland 20874. Upon information and belief, QIAGEN NA is the direct corporate parent of QIAGEN LLC and NeuMoDx, and is a wholly owned subsidiary of QIAGEN N.V.

9. Upon information and belief, Qiagen LLC is a limited liability company organized and existing under the laws of California, with its principal place of business at 19300 Germantown Road, Germantown, Maryland 20874. Upon information and belief, QIAGEN LLC was formerly known as QIAGEN, Inc. before converting to a California limited liability company in 2017. Upon information and belief, QIAGEN LLC is registered to conduct business in Delaware and, upon information and belief, conducts business in Delaware. Upon information and belief, QIAGEN LLC is a wholly owned subsidiary of QIAGEN NA and, ultimately, QIAGEN N.V.

FACTUAL ALLEGATIONS

Background

10. BD is a leading global medical technology company that is advancing the world of health by improving medical discovery, diagnostics, and the delivery of care. BD leads in patient and healthcare worker safety and the technologies that enable medical research and clinical laboratories. BD provides innovative solutions, including products that help advance medical

research, produces new drugs and vaccines, and enhances the diagnosis of infectious diseases and cancer.

11. In 2009, BD acquired HandyLab, a small biotechnology company developing bench-top devices for fast and early detection of diseases. HandyLab was originally founded in 1999 in Ann Arbor, Michigan by Kalyan Handique and Sundaresh Brahmasandra. Jeffrey Williams joined HandyLab as its CEO in 2004.

12. BD recognized HandyLab's emerging and nascent technology as promising, and in 2009, paid a substantial sum to acquire HandyLab, further develop that technology, integrate it with BD's own technology and expertise, and ultimately launch a diagnostics platform. In press releases, Williams stated that the "exclusive collaboration with BD represents an important step forward in expanding the utility" of HandyLab's platform, and that the collaboration with BD would "provide diagnostic laboratories with a broad molecular test menu on one of the industry's most advanced automation platform." *See* **Exhibit 7**. Funders of HandyLab called it "a big win for everybody." *See* **Exhibit 8**. As part of the acquisition, BD was granted an exclusive license to HandyLab's patented technologies as reflected in the Asserted Patents.

13. BD's acquisition of HandyLab set the stage for BD's next generation of molecular diagnostics platforms. BD invested heavily in developing the HandyLab technology, made numerous innovative improvements, and leveraged its own related diagnostics technologies, know-how and expertise, in creating and launching next generation molecular diagnostics platforms such as the BD MAX™ System—an automated molecular system designed to perform a broad range of molecular tests. The BD MAX™ System is a fully-integrated and fully-automated platform, incorporating clinical sample preparation, nucleic acid extraction, as well as microfluidic real-time polymerase chain reaction ("PCR") amplification and detection in a single diagnostic

system. The BD MAX™ System runs multiple specimen types and assays in a single run, providing highly sensitive and specific results in just a few hours. The system leverages a versatile menu and streamlined workflow to reduce total costs, and at short turnaround times that facilitate fast treatment decisions.

NeuMoDx

14. In 2012, Williams founded a company called "Molecular Systems Corp.," which ultimately became NeuMoDx. Months later, Brahmasandra, who had taken the position of Vice President of R&D Assay Development at BD after the HandyLab acquisition, joined NeuMoDx as President. Williams and Brahmasandra are named inventors on many of the Asserted Patents, and have long been aware of the inventions and patented technologies of the Asserted Patents.

15. NeuMoDx has been and is today utilizing the same patented technologies that BD acquired from HandyLab and developed into the BD MAX™ System. NeuMoDx has infringed and continues to infringe the Asserted Patents by making, using (including during research and development activities and product testing), offering for sale, selling, supplying and/or importing throughout and from the United States at least NeuMoDx's molecular diagnostics products , and/or inducing or contributing to such acts.

16. NeuMoDx's infringement has been and continues to be willful. Williams, Brahmasandra and other NeuMoDx employees are named inventors on the Asserted Patents, and, on information and belief, they and NeuMoDx have long been aware of the inventions and patented technologies of the Asserted Patents. Additionally, on information and belief, prior to and no later than September 2017, NeuMoDx conducted a review of third-party patents and identified many of the Asserted Patents and/or the patent applications resulting in the Asserted Patents as relevant to NeuMoDx's molecular diagnostics products. On information and belief, NeuMoDx also knew or

should have known that NeuMoDx's molecular diagnostics products were infringing but that it was acting despite an objectively high likelihood that its conduct would infringe the Asserted Patents. Nevertheless, NeuMoDx continued its willful and deliberate infringement of the Asserted Patents.

QIAGEN

17. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

18. QIAGEN is a multi-national organization that operates in the molecular diagnostics space. QIAGEN has direct operations in over 30 countries, including the United States. **Exhibit 94**.

19. On September 17, 2018, QIAGEN and NeuMoDx announced a strategic partnership to commercialize NeuMoDx's molecular diagnostic products through, upon information and belief, the execution of two contracts. **Exhibit 95**. The first agreement provided that QIAGEN would initially distribute NeuMoDx's molecular diagnostic products in Europe and other markets outside the United States, and that NeuMoDx would distribute directly within the United States. *Id.* The agreement further provided that NeuMoDx and QIAGEN would collaborate to develop certain functionalities for the NeuMoDx products. *Id.* In parallel, NeuMoDx and QIAGEN executed a merger agreement under which QIAGEN acquired a nearly 20% stake in NeuMoDx, and an option to acquire the remaining shares in NeuMoDx at a predetermined price, subject to NeuMoDx meeting certain milestones. QIAGEN announced its acquisition of the remaining 80.1% stake in NeuMoDx on September 17, 2020. **Exhibit 96**.

20. QIAGEN N.V., QIAGEN GmbH, QIAGEN North American Holdings, Inc., and QIAGEN LLC individually and collectively, directly and/or indirectly through their agents, alter-

egos, and subsidiaries under QIAGEN's control, have infringed and continue to infringe the Asserted Patents by making, using (including during research and development activities and product testing), offering for sale, selling, supplying and/or importing throughout and from the United States at least NeuMoDx's molecular diagnostics products, and/or inducing or contributing to such acts.

21. After Defendants executed the merger and distribution agreements in September 2018, QIAGEN launched the infringing NeuMoDx systems at the European Society of Clinical Virology congress later that month. As the foreign distributor of NeuMoDx's products under the September 2018 agreement, QIAGEN causes the infringing NeuMoDx products to be supplied from the United States and distributed throughout the world. On information and belief, following its European launch of the NeuMoDx systems, QIAGEN also began exhibiting the NeuMoDx systems at trade shows domestically and abroad where, upon information and belief, QIAGEN marketed, promoted, sold, and/or offered the NeuMoDx systems for sale. For example, QIAGEN's current CEO and then-Senior Vice President and Head of Molecular Diagnostics exhibited and marketed for sale the NeuMoDx molecular diagnostic systems at QIAGEN's booth at the November 2018 Association for Molecular Pathology conference in San Antonio, Texas. **Exhibit 97**. QIAGEN further induced NeuMoDx to continue its own infringement of the Asserted Patents by requiring that NeuMoDx continue "conduct[ing] its Business in the Ordinary Course of Business" under the 2018 merger agreement, *i.e.* requiring it to take actions that are "consistent with the past practices of the Company." **Exhibit 98**. Following its acquisition of NeuMoDx, QIAGEN has confirmed that "of course, we are [] selling this product on a global basis," including in the United States. **Exhibit 99**. Customers in the United States interested in ordering NeuMoDx products are now directed to "Order From" QIAGEN; are provided a QIAGEN address, phone

number, fax number, and email address for ordering; and told to "Remit [payment] to" QIAGEN. **Exhibit 100**. On information and belief, QIAGEN also provides customer support and accounting services in connection with its sales of the Accused Products. On information and belief, QIAGEN operates the https://go.qiagen.com/NeuMoDx website through which QIAGEN markets, promotes, advertises, offers demonstrations of, sells, and/or offers to sell the infringing NeuMoDx products.

22. QIAGEN's infringement has been and continues to be willful. On information and belief, prior to and no later than September 2018, QIAGEN conducted due diligence into NeuMoDx's technology and identified many of the Asserted Patents and/or the patent applications resulting in the Asserted Patents as relevant to NeuMoDx's molecular diagnostics products. Additionally, on information and belief, QIAGEN contacted Plaintiffs in late 2018 shortly after executing the merger agreement with NeuMoDx to reach an agreement regarding certain asserted patents, then filed petitions for *inter partes* review proceedings against certain asserted patents in December 2018. On information and belief, QIAGEN also knew or should have known that NeuMoDx's molecular diagnostics products were infringing but that it was acting despite an objectively high likelihood that its conduct would infringe the Asserted Patents. QIAGEN has nevertheless continued its willful and deliberate infringement of the Asserted Patents.

23. QIAGEN has a direct role in and directly controls this litigation. Pursuant to the Court's September 2, 2020 Order [D.I. 69], NeuMoDx was instructed to attend a mediation conference on October 23, 2020, and was required to be represented by counsel as well as "the party/parties and/or decisionmaker(s) of the parties, who must have full authority to act on behalf of the parties, including the authority to negotiate a resolution of the matter and to respond to developments during the mediation process." *See* [D.I. 69]. QIAGEN's Vice President, Global

IP & IP Litigation and QIAGEN's Senior Vice President, and Head of Molecular Diagnostics and Corporate Business Development & Intellectual Property & Litigation attended the mediation conference as the "decisionmaker(s)" empowered to act on behalf of NeuMoDx with regard to this litigation. No NeuMoDx employees attended the October 23, 2020 mediation as "the party/parties and/or decisionmaker(s) of the parties." Additionally, QIAGEN's outside counsel—Carlson Caspers Vandenburgh & Lindquist, PA.—have appeared as attorneys of record for NeuMoDx in this case.

24. NeuMoDx has represented that there is a common interest between NeuMoDx and QIAGEN. NeuMoDx has stated that, as of and before September 2020: (1) NeuMoDx and QIAGEN have a "relationship"; (2) QIAGEN has an "interest in NeuMoDx"; (3) QIAGEN is a distributor of NeuMoDx's products; (4) QIAGEN and NeuMoDx have "shared legal interests … in the anticipated and actual litigation with HandyLab/BD"—*i.e.*, this litigation; and (5) QIAGEN and NeuMoDx share "a common legal interest in dealing with intellectual property issues."

25. BD's past and future success as a company depends on its targeted investments in innovations that align with BD's business. BD integrates technologies across different applications to create next-generation innovations, including the BD MAX™ System for fully-integrated and fully-automated molecular diagnostics. BD's success depends on protecting those innovations, including the inventions claimed in the Asserted Patents.

26. As the direct and proximate result of Defendants' conduct, Plaintiffs have suffered, and if Defendants' conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs'

businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

The Asserted Patents

27. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

28. U.S. Patent No. 8,273,308 (the "'308 Patent"), entitled "Moving Microdroplets in a Microfluidic Device," was duly and legally issued on September 25, 2012 to inventors Kalyan Handique and Gene Parunak. A true and correct copy of the '308 Patent is attached as **Exhibit 1**.

29. U.S. Patent No. 8,703,069 (the "'069 Patent"), entitled "Moving Microdroplets in a Microfluidic Device" was duly and legally issued on April 22, 2014 to inventors Kalyan Handique and Gene Parunak. A true and correct copy of the '069 Patent is attached as **Exhibit 2**.

30. U.S. Patent No. 7,998,708 (the "'708 Patent"), entitled "Microfluidic System for Amplifying and Detecting Polynucleotides in Parallel" was duly and legally issued on August 16, 2011 to inventors Kalyan Handique, Sundaresh N. Brahmasandra, Karthik Ganesan, and Jeff Williams. A true and correct copy of the '708 Patent is attached as **Exhibit 3**.

31. U.S. Patent No. 8,323,900 (the "'900 Patent"), entitled "Microfluidic System for Amplifying and Detecting Polynucleotides in Parallel" was duly and legally issued on December 4, 2012 to inventors Kalyan Handique, Sundaresh N. Brahmasandra, Karthik Ganesan, and Jeff Williams. A true and correct copy of the '900 Patent is attached as **Exhibit 4**.

32. U.S. Patent No. 8,415,103 (the "'103 Patent"), entitled "Microfluidic Cartridge" was duly and legally issued on April 9, 2013 to inventor Kalyan Handique. A true and correct copy of the '103 Patent is attached as **Exhibit 5**.

33. U.S. Patent No. 8,709,787 (the "'787 Patent"), entitled "Microfluidic Cartridge and Method of Using Same" was duly and legally issued on April 29, 2014 to inventor Kalyan Handique. A true and correct copy of the '787 Patent is attached as **Exhibit 6**.

34. U.S. Patent No. 10,494,663 (the "'663 Patent"), entitled "Method for Processing Polynucleotide-Containing Samples" was duly and legally issued on December 3, 2019 to inventors Betty Wu, John S. Althaus, Nikhil Phadke, Sundaresh N. Brahmasandra, Kalyan Handique, Aaron Kehrer, Gene Parunak, Cecelia Haley, and Ted Springer. A true and correct copy of the '663 Patent is attached as **Exhibit 46**.

35. U.S. Patent No. 10,364,456 (the "'456 Patent"), entitled "Method for Processing Polynucleotide-Containing Samples" was duly and legally issued on July 30, 2019 to inventors Betty Wu, John S. Althaus, Nikhil Phadke, Sundaresh N. Brahmasandra, Kalyan Handique, Aaron Kehrer, Gene Parunak, Cecelia Haley, and Ted Springer. A true and correct copy of the '456 Patent is attached as **Exhibit 43**.

36. U.S. Patent No. 10,443,088 (the "'088 Patent"), entitled "Method for Processing Polynucleotide-Containing Samples" was duly and legally issued on October 15, 2019 to inventors Betty Wu, John S. Althaus, Nikhil Phadke, Sundaresh N. Brahmasandra, Kalyan Handique, Aaron Kehrer, Gene Parunak, Cecelia Haley, and Ted Springer. A true and correct copy of the '088 Patent is attached as **Exhibit 44**.

37. U.S. Patent No. 10,604,788 (the "'788 Patent"), entitled "System for Processing Polynucleotide-Containing Samples" was duly and legally issued on March 31, 2020 to inventors Betty Wu, John S. Althaus, Nikhil Phadke, Sundaresh N. Brahmasandra, Kalyan Handique, Aaron Kehrer, Gene Parunak, Cecelia Haley, and Ted Springer. A true and correct copy of the '788 Patent is attached as **Exhibit 45**.

38. U.S. Patent No. 10,625,261 (the "'261 Patent"), entitled "Integrated Apparatus for Performing Nucleic Acid Extraction and Diagnostic Testing on Multiple Biological Samples" was duly and legally issued on April 21, 2020 to inventors Jeff Williams, Kerry Wilson, and Kalyan Handique. A true and correct copy of the '261 Patent is attached as **Exhibit 40**.

39. U.S. Patent No. 10,625,262 (the "'262 Patent"), entitled "Integrated Apparatus for Performing Nucleic Acid Extraction and Diagnostic Testing on Multiple Biological Samples" was duly and legally issued on April 21, 2020 to inventors Jeff Williams, Kerry Wilson, and Kalyan Handique. A true and correct copy of the '262 Patent is attached as **Exhibit 41**.

40. U.S. Patent No. 10,632,466 (the "'466 Patent"), entitled "Integrated Apparatus for Performing Nucleic Acid Extraction and Diagnostic Testing on Multiple Biological Samples" was duly and legally issued on April 28, 2020 to inventors Jeff Williams, Kerry Wilson, and Kalyan Handique. A true and correct copy of the '466 Patent is attached as **Exhibit 42**.

41. As explained above, Williams, Brahmasandra, and other NeuMoDx employees are named inventors on the Asserted Patents, and, on information and belief, they and NeuMoDx have long been aware of the Asserted Patents. Additionally, NeuMoDx also had knowledge of the '308, '708, '900, '103, and '787 Patents, as evidenced by numerous citations by NeuMoDx to these patents during the prosecution of NeuMoDx patents. For example, on May 28, 2014, the '308, '708, '900, and '103 Patents were cited in an Information Disclosure Statement submitted during the prosecution of NeuMoDx patent, U.S. Patent No. 9,050,594, and those four patents were subsequently cited or discussed in the prosecution of at least U.S. Patent No. 9,382,532, U.S. Patent No. 9,738,887, U.S. Patent No. 9,433,940, and U.S. Patent No. 9,339,812. On June 2, 2014, the '787 Patent was cited in an Office Action by the patent examiner during the prosecution of NeuMoDx patent, U.S. Patent No. 9,101,930. On information and belief, prior to and no later than

September 2017, NeuMoDx conducted a third-party patent review and identified many of the Asserted Patents and/or the patent applications resulting in the Asserted Patents as relevant to NeuMoDx's molecular diagnostics products. On information and belief, NeuMoDx also had knowledge of at least the '708 and '900 Patents at least of December 2018, when petitions for *inter partes* review proceedings, IPR2019-00488 and IPR2019-00490, were filed against those patents. NeuMoDx also had knowledge of many of the Asserted Patents at least as a result of BD's December 21, 2018 email to Williams attaching a spreadsheet identifying U.S. Patent Nos. 8,273,308, 8,703,069, 7,998,708, 8,323,900, and 8,415,103, as well as patent titles, exemplary claims, and expiration dates. *See* **Exhibit 9**. NeuMoDx was additionally put on notice of the '663, '456, '088, and '788 Patents when they were identified in Plaintiffs' disclosures to NeuMoDx on April 13, 2020.

42. On information and belief, QIAGEN has long been aware of the Asserted Patents. QIAGEN is a sophisticated entity in the molecular diagnostics field, and admits that it "follow[s] developments in this field" and is "aware that patents have been applied for and/or issued to third parties claiming technologies for sample and assay technologies that are closely related to those [it] use[s]." **Exhibit 101**. On information and belief, prior to and no later than September 2018, QIAGEN also conducted due diligence into NeuMoDx's technology and identified many of the Asserted Patents and/or the patent applications resulting in the Asserted Patents as relevant to NeuMoDx's molecular diagnostics products. On information and belief, QIAGEN also had knowledge of at least the '708 and '900 Patents at least as of December 2018, when it filed petitions for *inter partes* review proceedings, IPR2019-00488 and IPR2019-00490, against those patents. On information and belief, no later than June 18, 2019, QIAGEN has been aware of the Asserted Patents as they have been disclosed over the course of this litigation. Furthermore, QIAGEN was

aware of each of the Asserted Patents no later than October 23, 2020, when QIAGEN's in-house represented NeuMoDx at a mediation conference in connection with this litigation.

DEFENDANTS' INFRINGING PRODUCTS

43. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

44. Exemplary infringement charts, attached as **Exhibits 34-39 and 86-92,** detail Defendants' infringement of the Asserted Patents. These descriptions are not intended to limit Plaintiffs' right to amend, supplement, or modify these descriptions or any other analysis, description, or claim chart or allege that other activities of Defendants infringe the identified claims or any other claims of these patents or any other patents.

45. Defendants manufacture, use, sell, offer for sale and/or import molecular diagnostics systems, instruments, consumables, accessories, test strips, and reagents (the "Accused Products" or "Molecular Diagnostics Products"). The Accused Products include the NeuMoDx™ 288 Molecular System (Product Code 500100) and NeuMoDx™ 96 Molecular System (Product Code 500200), and any products or components that are imported, made, used, sold, and/or offered for sale by or on behalf of Defendants in connection with and/or as part of the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems, or any other NeuMoDx products that embody like functionality, including without limitation the NeuMoDx™ Cartridge (Product Code 100100); NeuMoDx™ GBS Test Strip (Product Code 200400); NeuMoDx™ CT/NG Test Strip (Product Code 200300); NeuMoDx™ HBV Quant Test Strip (Product Code 201300); NeuMoDx™ HCV Quant Test Strip (Product Code 300300); NeuMoDx™ CMV Quant Test Strip (Product Code 201400); NeuMoDx™ EBV Quant Test Strip (Product Code 201500); NeuMoDx™ Strep A/C/G Vantage Test Strip (Product Code 201902); NeuMoDx™ TV/MG Test Strip (Product Code

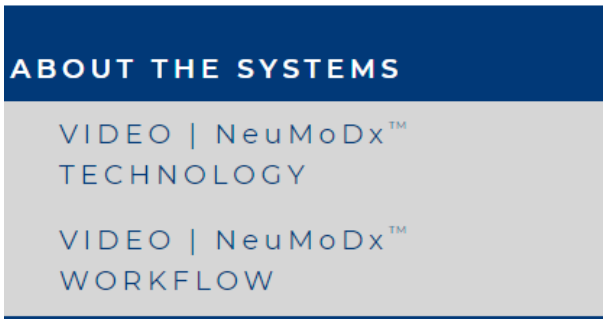
201200); NeuMoDx™ CT/NG Test Strip, IUO (Product Code 200301); NeuMoDx™ HIV-1 Quant Test, RUO (Product Code 300509); HPV Test Strip, RUO (Product Code 617008); NeuMoDx™ HIV-1 Calibrator, RUO (Product Code 800319); NeuMoDx™ HIV-1 External Controls, RUO (Product Code 900309); NeuMoDx™ LDT Master Mix, DNA (Product Code 210100); NeuMoDx™ LDT Master Mix, RNA (Product Code 310100); NeuMoDx™ LDT Primer/Probe Strip (Product Code 100400); NeuMoDx™ Lysis Buffer 1 (Product Code 400400); NeuMoDx™ Lysis Buffer 2 (Product Code 400500); NeuMoDx™ Lysis Buffer 3 (Product Code 400600); NeuMoDx™ Lysis Buffer 4 (Product Code 400700); NeuMoDx™ Lysis Buffer 5 (Product Code 400900); NeuMoDx™ Lysis Buffer 6 (Product Code 401700); NeuMoDx™ Viral Lysis Buffer (Product Code 401600); NeuMoDx™ HBV Calibrators (Product Codes 800100, 800102); NeuMoDx™ HBV External Controls (Product Codes 900101, 900102); NeuMoDx™ HCV Calibrators (Product Codes 800200, 800202); NeuMoDx™ HCV External Controls (Product Codes 900201, 900202); NeuMoDx™ CMV Calibrators (Product Code 800400); NeuMoDx™ CMV External Controls (Product Code 900401); NeuMoDx™ EBV Calibrators (Product Code 800500); NeuMoDx™ EBV External Controls (Product Code 900501); NeuMoDx™ Wash Reagent (Product Code 400100); NeuMoDx™ Release Reagent (Product Code 400200); NeuMoDx™ Extraction Plate (Product Code 100200); NeuMoDx™ CO-RE-Tips 300 µL with Filters (Product Code 235903); NeuMoDx™ CO-RE-Tips 1000 µL with Filters (Product Code 235905); NeuMoDx™ 96 Priming Waste Bottle (Product Code 400800); NeuMoDx™ 288 Priming Waste Bottle (Product Code 400300); NeuMoDx™ 288 Waste Chute (Product Code 600800); NeuMoDx™ Biohazard Waste Bag (Product Code 600100); NeuMoDx™ Biohazard Waste Container (Product Code 600200); NeuMoDx™ Test Strip Carrier (Product Code 600300); NeuMoDx™ Buffer Carrier (Product Code 600400); NeuMoDx™ Tip, Extraction Plate and Filter

Carrier (Product Code 600500); Specimen Tube Carrier (32 Tube) (Product Code 173410); Specimen Tube Carrier (24 Tube) (Product Code 173400); NeuMoDx™ Cartridge Carrier (Product Code 600700); NeuMoDx™ Tip Tray (Product Code 601200); NeuMoDx™ 96 Biohazard Tip Waste Bin (Product Code 600900); NeuMoDx™ 96 Biohazard Tip Waste Bag (Product Code 601000); NeuMoDx™ 96 Biohazard Waste Bin (Product Code 601100); NeuMoDx™ Mobile Worktable, N96 (Product Code 601300); NeuMoDx™ DEMO Kit 96 (Product Code 700304); NeuMoDx™ DEMO Kit 288 (Product Code 700401); NeuMoDx™ 288 Molecular System DEMO (Product Code 500100-DEMO); and NeuMoDx™ 96 Molecular System DEMO (Product Code 500200-DEMO).

46. Defendants manufacture, use, sell, offer for sale and/or import the Accused Products as indicated on their websites, and market the Accused Products as competing with the BD MAX™ System.[1]

47. The NeuMoDx website links or linked to videos that illustrate the form and function of the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems, including: (1) a video directed to the NeuMoDx™ technology, which links to a Vimeo hyperlink, https://vimeo.com/281470603, and (2) a video directed to the NeuMoDx™ workflow, which linked to a Vimeo hyperlink, https://vimeo.com/299307936 (as of June 18, 2019).[2]

[1] *See* https://www.neumodx.com/our-products/; https://www.neumodx.com/client-resources/instructions-for-use-english/; https://go.qiagen.com/NeuMoDx.
[2] *See* https://www.neumodx.com/our-solutions/.



48. QIAGEN's website further provides brochures and videos, including a "Virtual Showcase" on the NeuMoDx systems, that describe the technology and workflow of the NeuMoDx™ technology.[3]

49. NeuMoDx also marks its products on its website by patent number.[4] NeuMoDx marks its cartridge products with the following patent numbers: U.S. Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430; as well as AU Patent No. 2013221701; and JP Patent No. 6061313. NeuMoDx marks its P02 (overall system and method) products with the following patent numbers: U.S. Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888; as well as CN Patent No. ZL 2013 8 00092863. NeuMoDx marks its extraction plate products with the following patent numbers: U.S. Patent Nos. 9,382,532, and 9,540,636; as well as DE Patent No. 60 2013 056 932.0; DK Patent No. 2912174; EP Patent No. EP-B-2912174; ES Patent No. 300330453; FR Patent No. 2912174; GB Patent No. 2912174; IT Patent No. 502019000064944; NO Patent No. 2912174; and SE Patent No. 2912174. NeuMoDx marks its XPCR module products with the following patent numbers: U.S. Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.

[3] https://go.qiagen.com/NeuMoDx; https://go.qiagen.com/NeuMoDxVirtualShowcase.
[4] *See* https://www.neumodx.com/patents/.

References to the NeuMoDx marking webpage can be found on NeuMoDx product literature, including Instructions for Use documents. *See, e.g.,* **Exhibit 19**.

PATENTS

Product	Patents
CARTRIDGE	US Patent Nos. 9,738,887; 9,433,940; 9,101,930; 9,403,165; and 9,452,430. AU Patent No. 2013221701. JP Patent No. 6061313.
P02 (overall system and method)	US Patent Nos. 9,050,594; 9,339,812; 9,441,219; 10,041,062; 9,604,213; and 10,010,888. CN Patent No. 201380009286.3.
EXTRACTION PLATE	US Patent Nos. 9,382,532; and 9,540,636. DE Patent No. 60 2013 056 932.0. DK Patent No. 2912174. EP Patent No. EP-B-2912174. ES Patent No. 300330453. FR Patent No. 2912174. GB Patent No. 2912174. IT Patent No. 502019000064944. NO Patent No. 2912174. SE Patent No. 2912174.
XPCR MODULE	US Patent Nos. 9,499,896; 10,239,060; 9,539,576; 10,226,771; 9,637,775; 10,093,963; 9,604,213; and 10,010,888.

JURISDICTION AND VENUE

50. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

51. Plaintiffs bring this action for patent infringement by Defendants arising under the patent laws of the United States, Title 35 of the United States Code. Accordingly, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

52. This Court has personal jurisdiction over NeuMoDx because, *inter alia*, NeuMoDx is incorporated in Delaware, and committed, aided, abetted, induced, contributed to, and/or participated in the commission of tortious acts of patent infringement that have led to foreseeable

harm and injury to Plaintiffs in Delaware. Moreover, NeuMoDx has substantial contacts with the forum as a consequence of being incorporated in Delaware and, upon information and belief, conducting business in Delaware.

53. This Court has personal jurisdiction over QIAGEN under 10 Del. C. § 3104, and other applicable law, because, *inter alia*, QIAGEN has purposefully availed itself of the rights and benefits of the laws of Delaware, such that it should reasonably anticipate being subject to suit here. Upon information and belief, the QIAGEN entities work in concert either directly or indirectly through one or more wholly-owned subsidiaries of QIAGEN over which they exercise control, agents and/or alter egos, with respect to the marketing, importation, offer for sale, sale and distribution of infringing NeuMoDx products throughout the United States, including in this judicial district.

54. This Court has personal jurisdiction over QIAGEN N.V. because, *inter alia*, QIAGEN N.V. regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware directly and/or indirectly through its agents, alter-egos, and subsidiaries over which it exercises control that has led to foreseeable harm and injury to Plaintiffs in Delaware. Furthermore, this Court has personal jurisdiction over QIAGEN N.V. because QIAGEN N.V. has committed, aided, abetted, induced, contributed to, and/or participated in the commission of tortious acts of patent infringement that have led to foreseeable harm and injury to Plaintiffs in Delaware. Additionally, at least QIAGEN N.V.'s CEO stated on QIAGEN N.V.'s Q3 shareholder call that "we are [] selling this product on a global basis," referring to the Accused Products and including the United States. **Exhibit 99**. At least QIAGEN N.V. executives also participate in trade shows across the United States where QIAGEN exhibits, promotes, and sells or offers to sell NeuMoDx products. For example, at least QIAGEN N.V.'s current CEO and then-Senior Vice

President and Head of Molecular Diagnostics exhibited and marketed for sale the NeuMoDx molecular diagnostic systems at QIAGEN's booth at the November 2018 Association for Molecular Pathology conference in San Antonio, Texas. **Exhibit 97**. Upon information and belief, the conference attendees exhibited and marketed-to included representatives of Delaware corporations, including, for example, Bristol-Meyers Squibb, Asuragen, Inc., and Thermo Fisher Scientific, Inc. Additionally, at least QIAGEN N.V. presents and promotes the accused products at academic and industry conferences and roadshows throughout the United States. For example, and on information and belief, at least QIAGEN N.V.'s CEO and/or other top QIAGEN N.V. executives marketed the NeuMoDx systems at the 2019 and 2020 J.P. Morgan Health Conferences in San Francisco, California, the 2019 Morgan Stanley Healthcare Conference and 2019 Jefferies Healthcare Conference in New York, New York, and the 2019 Barclays Healthcare Conference in Miami, Florida.[5] Moreover, Defendants have named QIAGEN N.V. as a real party-in-interest in each of the IPRs Defendants have filed against the Asserted Patents. *See* IPR2019-00488, Paper 1; IPR2019-01493, Paper 2; IPR2020-01083, Paper 2; IPR2020-01091, Paper 2; IPR2019-00490, Paper 1; IPR2019-01494, Paper 2; IPR2020-01133, Paper 2; IPR2020-01136, Paper 2; IPR2020-01100, Paper 3; IPR2020-01095, Paper 2; IPR2020-01132, Paper 2; IPR2020-01137, Paper 2; IPR2021-00251, Paper 2; IPR2021-00250, Paper 2; and IPR2021-00253, Paper 2. Furthermore, QIAGEN N.V. has purposefully availed itself of the rights and benefits of the laws of Delaware at least through the incorporation of multiple of its wholly owned subsidiaries under the laws of Delaware, including, for example, NeuMoDx.

[5] https://corporate.qiagen.com/investor-relations/events-and-presentations#events_o=End%20Date,Descending&events_End%20Date=20200101|20201214&events_Event%20category=conferences%20and%20roadshows.

55. This Court has personal jurisdiction over QIAGEN GmbH because, *inter alia*, QIAGEN GmbH regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware directly and/or indirectly through its agents, alter-egos, and subsidiaries over which it exercises control that has led to foreseeable harm and injury to Plaintiffs in Delaware. Furthermore, this Court has personal jurisdiction over QIAGEN GmbH because QIAGEN GmbH has committed, aided, abetted, induced, contributed to, and/or participated in the commission of tortious acts of patent infringement that have led to foreseeable harm and injury to Plaintiffs in Delaware. Upon information and belief, at least QIAGEN GmbH maintains and operates websites at https://www.qiagen.com/us/ and https://go.qiagen.com/NeuMoDx that are accessible in Delaware and through which at least QIAGEN GmbH directly and/or indirectly through its agents, alter-egos, or other affiliated company it controls, is controlled by, or is under common control with promotes, advertises, sells, and offers for sale the accused products to customers in the United States, including Delaware. Furthermore, and upon information and belief, at least QIAGEN GmbH distributes the accused products in Europe and other major markets outside of the United States. Therefore, upon information and belief, at least QIAGEN GmbH causes the infringing products to be supplied from the United States, leading to foreseeable harm and injury to Plaintiffs in Delaware. Furthermore, QIAGEN's wholly owned subsidiary, NeuMoDx, has asserted an affirmative defense in this litigation based on an alleged license and supply agreement between QIAGEN GmbH and HandyLab. Disputes about the license and supply agreement, including the scope of the alleged license, are to be resolved in Delaware under Delaware law.

56. Moreover, at least QIAGEN N.V. and QIAGEN GmbH have consented, acquiesced, waived objection to, and otherwise purposefully availed themselves of the rights and benefits of the laws of Delaware in connection with this litigation. For example, and specifically

incorporating Paragraph 23 above, QIAGEN N.V. and QIAGEN GmbH have at least consented, acquiesced, waived objection to litigation in this District by participating in mediation conferences on behalf of NeuMoDx in connection with this litigation.

57. Alternatively, this Court has personal jurisdiction over QIAGEN N.V. and QIAGEN GmbH under Federal Rule of Civil Procedure 4(k)(2), because, *inter alia*, QIAGEN N.V. and QIAGEN GmbH have sufficient contacts with the United States as a whole, including in Delaware, such that this Court's exercise of jurisdiction over QIAGEN N.V. and QIAGEN GmbH satisfies due process.

58. This Court has personal jurisdiction over QIAGEN NA because, *inter alia*, QIAGEN NA regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware directly and/or indirectly through its agents, alter-egos, and subsidiaries which it directs and over which it exercises control (including, *e.g.*, NeuMoDx and QIAGEN LLC) that has led to foreseeable harm and injury to Plaintiffs in Delaware. Furthermore, this Court has personal jurisdiction over QIAGEN NA because QIAGEN NA has committed, aided, abetted, induced, contributed to, and/or participated in the commission of tortious acts of patent infringement (including by, *e.g.*, its wholly-owned subsidiaries NeuMoDx and QIAGEN LLC) that have led to foreseeable harm and injury to Plaintiffs in Delaware. For example, QIAGEN NA and NeuMoDx executed a merger agreement and subsequent amendment pursuant to which QIAGEN NA obligated NeuMoDx, which resides in Delaware, to continue its ongoing, infringing course of business. The merger agreement and subsequent amendment were executed under Delaware law, and are subject to a Delaware forum selection clause. Moreover, Defendants have named QIAGEN NA as a real party-in-interest in each of the IPRs Defendants have filed against the Asserted Patents. *See* IPR2019-00488, Paper 1; IPR2019-01493, Paper 2; IPR2020-01083,

Paper 2; IPR2020-01091, Paper 2; IPR2019-00490, Paper 1; IPR2019-01494, Paper 2; IPR2020-01133, Paper 2; IPR2020-01136, Paper 2; IPR2020-01100, Paper 3; IPR2020-01095, Paper 2; IPR2020-01132, Paper 2; IPR2020-01137, Paper 2; IPR2021-00251, Paper 2; IPR2021-00250, Paper 2; and IPR2021-00253, Paper 2. At least QIAGEN NA further induced NeuMoDx—a Delaware corporate—to continue its own infringement of the Asserted Patents by requiring that NeuMoDx continue "conduct[ing] its Business in the Ordinary Course of Business" under the 2018 merger agreement, *i.e.* requiring it to take actions that are "consistent with the past practices of the Company." Furthermore, at least QIAGEN NA has purposefully availed itself of the rights and benefits of the laws of Delaware at least through the incorporation of its wholly owned subsidiaries under the laws of Delaware, including NeuMoDx.

59. This Court has personal jurisdiction over QIAGEN LLC because, *inter alia*, QIAGEN LLC regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware directly and/or indirectly through its agents, alter-egos, and subsidiaries over which it exercises control that has led to foreseeable harm and injury to Plaintiffs in Delaware. Furthermore, this Court has personal jurisdiction over QIAGEN LLC because QIAGEN LLC has committed, aided, abetted, induced, contributed to, and/or participated in the commission of tortious acts of patent infringement that have led to foreseeable harm and injury to Plaintiffs in Delaware. Upon information and belief, at least QIAGEN LLC, either directly or indirectly, sells or offers the infringing products for sale throughout the United States, including in Delaware. On information and belief, at least QIAGEN LLC also provides customer support and accounting services in connection with its sales of the Accused Products, to customers throughout the United States, including in Delaware. Moreover, QIAGEN LLC has substantial contacts with the forum

as a consequence of being registered to conduct business in Delaware and, upon information and belief, conducting business in Delaware.

60. Upon information and belief, Defendants work in concert either directly or indirectly through one or more QIAGEN entities or wholly-owned subsidiaries of QIAGEN—including NeuMoDx, over which QIAGEN exercises control—agents, and/or alter egos with respect to the marketing, importation, offer for sale, sale and distribution of infringing NeuMoDx products throughout the United States, including in this judicial district.

61. Upon information and belief, Defendants operate as a single integrated business, and act jointly, in concert with, and/or through one another to infringe the Asserted Patents. Upon information and belief, there is such domination, a unity of interest and control between the Defendants that they cannot readily be said to operate as separate entities. For example, QIAGEN N.V.'s CEO stated on QIAGEN's 2020 Q3 shareholder call that "[w]e are now integrating NeuMoDx into QIAGEN"; that, through NeuMoDx, QIAGEN has "direct access to the U.S. market and an existing installed base"; and that "[w]ith the U.S. placements we are now at 110 installed systems worldwide and growing." **Exhibit 99**. Furthermore, QIAGEN N.V. describes the NeuMoDx systems in its 2019 Annual Report as one of "*our*" systems, and indicates that "*[o]ur assay development program* aims to commercialize tests that will add value to *our* … NeuMoDx … automation systems." **Exhibit 101** (emphasis added). The Report further states that "[o]ur continued growth depends significantly on the success of new products in the molecular testing markets we serve," one such "[i]mportant new product program" being the accused NeuMoDx systems. *Id.* Moreover, and without distinguishing between the QIAGEN entities, QIAGEN N.V. has variously stated in its Annual Reports, SEC filings, and shareholder calls that "*Qiagen* offers an extensive range of kits for diagnosing infectious diseases, including a broad menu of tests on

the . . . NeuMoDx automation systems," and that "*we*" are "accelerating the ramp-up of NeuMoDx," "implementing plans to significantly scale not only production capabilities but also the test menu, especially for the United States," and "expanding [the NeuMoDx] portfolio by seeking regulatory approvals of new assays." **Exhibits 99, 101**.

62. Upon information and belief, at least QIAGEN GmbH, QIAGEN NA, QIAGEN LLC, and NeuMoDx act at the direction, and for the benefit, of QIAGEN N.V.; are controlled and/or dominated by QIAGEN N.V.; and are agents and/or alter-egos of one another and QIAGEN N.V. For example, QIAGEN N.V. has stated that "[a]s a holding company, QIAGEN conducts business through subsidiaries located throughout the world," and that "QIAGEN N.V. is dependent upon payments, dividends and distributions from the subsidiaries for funds to pay operating and other expenses as well as to pay future cash dividends or distributions," thus making clear that QIAGEN N.V. controls its subsidiaries, are one and the same as its subsidiaries, and direct and depend upon its subsidiaries to serve the United States molecular diagnostics market. **Exhibit 101**.

63. Furthermore, upon information and belief, QIAGEN N.V. exercises close supervisory control over and directs the day-to-day operations of QIAGEN GmbH, QIAGEN NA, QIAGEN LLC, and NeuMoDx. For example, QIAGEN N.V. has recently stated in its SEC filings that "[w]e operate as one operating segment . . . We have a common basis of organization and our products and services are offered globally. Our chief operating decision maker (CODM) makes decisions based on the Company as a whole. Accordingly, we operate and make decisions as one reporting unit." **Exhibit 102**. Furthermore, QIAGEN N.V. has admitted in prior litigation that "QIAGEN shares a single Executive Committee," that the members of the Executive Committee "share powers and responsibilities for the operational management of the Company and the

achievement of its objectives and results," and that "individuals on the executive committee are employees of various QIAGEN subsidiaries." *See Illumina, Inc. v. QIAGEN, N.V. et al.*, No. 16-cv-02788-WHA, QIAGEN N.V.'s Answer to Complaint for Patent Infringement [D.I. 90] (N.D. Cal.). Upon information and belief, there is significant overlap in management and control between QIAGEN N.V. and its subsidiaries. Upon information and belief, QIAGEN N.V.'s CEO, who also serves on QIAGEN N.V.'s Managing Board and QIAGEN N.V.'s Executive Committee, also serves as the CEO Qiagen LLC, the CEO of QIAGEN NA, and is the sole director of QIAGEN NA. **Exhibits 103-105**. Upon information and belief, the CFO of Qiagen N.V. also serves on QIAGEN N.V.'s Managing Board, QIAGEN N.V.'s Executive Committee, and is also the CFO of Qiagen NA and Qiagen LLC. *Id*. Furthermore, upon information and belief, QIAGEN's GmbH's Senior Vice President of Molecular Diagnostics and Corporate Development also serves on QIAGEN N.V.'s Executive Committee, and represented NeuMoDx at the October 23 mediation conference in this litigation. QIAGEN's Vice President, Global IP & IP Litigation at QIAGEN GmbH also represented NeuMoDx at the October 23 mediation conference.

64. Moreover, on information and belief, there is such significant overlap and lack of corporate separateness between the U.S. QIAGEN subsidiaries that it would be unjust and inequitable for them to be treated separately. On information and belief, in addition to sharing the same CEO and CFO, QIAGEN NA and QIAGEN LLC also share other executive officers, such as the same secretary. **Exhibits 104-105**. Furthermore, on information and belief, QIAGEN LLC has no managers, and there is only one member of the LLC: QIAGEN NA. QIAGEN NA and QIAGEN LLC also share the same principal place of business at 19300 Germantown Road, Germantown, Maryland 20874. Upon information and belief, QIAGEN NA and QIAGEN LLC are so closely related and devoid of separate corporate identities that the acts of one are attributable

to the other. For example, upon information and belief, QIAGEN NA has held itself out as doing business as QIAGEN LLC in connection with sales of QIAGEN-affiliated products in the United States. **Exhibit 106.** As to NeuMoDx, following the closing of the acquisition of NeuMoDx by QIAGEN NA, NeuMoDx has rebranded itself as NeuMoDx Molecular, "a QIAGEN company," thus making clear that NeuMoDx is subject to the control of the QIAGEN group.

Furthermore, customers attempting to order products from NeuMoDx following the merger are now automatically redirected to QIAGEN's website. Moreover, pursuant to the merger agreement between QIAGEN NA and NeuMoDx, the entire Board of Directors of NeuMoDx was required to step down upon the acquisition to be replaced with QIAGEN appointees. On information and belief, neither QIAGEN nor NeuMoDx have announced a single new board member of NeuMoDx, despite the merger closing three months ago. Moreover, Defendants have named NeuMoDx as a real party-in-interest in each of the IPRs Defendants have filed against the Asserted Patents. *See* IPR2019-00488, Paper 15; IPR2019-01493, Paper 2; IPR2020-01083, Paper 2; IPR2020-01091, Paper 2; IPR2019-00490, Paper 15; IPR2019-01494, Paper 2; IPR2020-01133, Paper 2; IPR2020-01136, Paper 2; IPR2020-01100, Paper 3; IPR2020-01095, Paper 2; IPR2020-01132, Paper 2; IPR2020-01137, Paper 2; IPR2021-00251, Paper 2; IPR2021-00250, Paper 2; and IPR2021-00253, Paper 2.

65. Upon information and belief, Defendants intend to serve the United States market, including the Delaware market specifically. Furthermore, and upon information and belief, this

Court has personal jurisdiction over Defendants under 10 Del. C. § 3104, Federal Rule of Civil Procedure 4(k)(2), and other applicable law, because, *inter alia*, Defendants, either directly or indirectly, have continuously and systematically placed goods into the stream of commerce for distribution throughout the United States, including Delaware, and have committed, aided, abetted, induced, contributed to, and/or participated in the commission of tortious acts of patent infringement that have led to foreseeable harm and injury to Plaintiffs in Delaware.

66. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein. Venue is proper in this District under at least 28 U.S.C. § 1400(b), § 1391, and pendent venue. Venue is proper in this District for NeuMoDx because NeuMoDx is a Delaware corporation that, upon information and belief, conducts business in Delaware. Venue is proper in this District for QIAGEN at least because, upon information and belief, QIAGEN's agents and/or alter-egos are subject to venue in the District. Venue in this District is also proper for QIAGEN at least because, upon information and belief, QIAGEN directs, controls, or acts in concert with one or more wholly-owned QIAGEN subsidiaries residing in this District to infringe the Asserted Patents. Furthermore, venue is also proper in this District under 28 U.S.C. § 1391 because QIAGEN N.V. and QIAGEN GmbH are foreign defendants that are subject to the personal jurisdiction of this Court. Venue is also proper in this district by virtue of the forum selection clause contained within an alleged prior license and supply agreement between HandyLab and QIAGEN GmbH, which NeuMoDx has brought into dispute in this litigation, and which is binding on QIAGEN GmbH. That forum selection clause states that the "parties consent to exclusive jurisdiction for any disputes arising under this Agreement in any state or Federal courts situated in Delaware." Delaware is also the most convenient forum, and litigating this action in Delaware is in the interests of justice, under 28 U.S.C. § 1404(a).

COUNT 1
(INFRINGEMENT OF THE '308 PATENT)

67. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

68. On information and belief, Defendants directly or through the actions of their employees, agents, distributors, divisions, and/or subsidiaries, have infringed and continue to infringe, one or more of the claims of the '308 Patent, including at least claims 1, 18, and 19, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or supplying and/or importing the Accused Products throughout and from the United States, and/or inducing or contributing to such acts, without authority.

69. For example, the Accused Products meet each element of, and infringe, claim 1, which states:

Claim 1. A system, comprising:
a microfluidic device;
a computer-controlled heat source; and
a detector;
wherein the microfluidic device comprises:
an upstream channel;
a DNA manipulation module located downstream from the upstream channel;
a DNA manipulation zone within the DNA manipulation module and configured to perform PCR amplification of a sample;
a first valve disposed within the DNA manipulation module upstream of the DNA manipulation zone;
a second valve disposed within the DNA manipulation module downstream of the DNA manipulation zone; and
a vent disposed within the DNA manipulation module and separated from the upstream channel by the first and second valves;
a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the DNA manipulation zone when amplification of the sample occurs, wherein the only ingress to and egress from the DNA manipulation zone is through the first and second valves, and wherein the

computer-controlled heat source is in thermal contact with the DNA manipulation zone; and

wherein the detector is configured to identify one or more polynucleotides within the DNA manipulation zone.

70. The Accused Products also meet each element of, and infringe, claim 18, which states:

Claim 18. A device, comprising:
a microfluidic process module;
a computer-controlled heat source; and
a detector;
wherein the microfluidic process module comprises:
a zone configured to receive a sample and perform amplification of the sample;
a first valve upstream of the zone;
a second valve downstream of the zone; and
a vent separated from the first valve by the second valve;
a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the zone when amplification of the sample occurs in the zone, wherein the only ingress to and egress from the zone is through the first and second valves;
wherein the computer-controlled heat source is in thermal contact with the zone; and
wherein the detector is configured to identify one or more polynucleotides within the zone.

71. The Accused Products also meet each element of, and infringe, claim 19, which states:

Claim 19. A system, comprising:
a microfluidic device;
a computer-controlled heat source; and
a detector;
wherein the microfluidic device comprises:
an upstream channel;
a DNA manipulation zone located downstream from the upstream channel and configured to perform PCR amplification of a sample;
a first valve disposed upstream of the DNA manipulation zone; and
a second valve disposed downstream of the DNA manipulation zone;
a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the DNA manipulation zone and to isolate and confine the sample to a region between the first and second valves accessible to the detector, wherein the only ingress to and egress from the region accessible to the detector is through the first and second valves; and

wherein the computer-controlled heat source is in thermal contact with the DNA manipulation zone and wherein the detector is configured to identify one or more polynucleotides within the DNA manipulation zone.

72. Defendants infringe each element of claims 1, 18, and 19 of the '308 Patent. Defendants' own documents, publicly posted videos, and patents that are marked on NeuMoDx products show that the Accused Products infringe the claims of the '308 Patent. As an example, U.S. Patent No. 8,273,308 Preliminary and Exemplary Claim Chart, detailing Defendants' infringement of these claims of the '308 Patent, is attached as **Exhibit 34**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of Defendants infringe the identified claims or any other claims of the '308 Patent or any other patents. **Exhibit 34** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 34** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

73. Defendants have also induced and currently induce infringement of the '308 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, Defendants know infringes the '308 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, NeuMoDx has known of the '308 Patent and of its infringement since at least September 2017, and QIAGEN has known of the '308 Patent and of its infringement since at least September 2018. By providing its customers with the Accused Products and those instructions for use, Defendants specifically intend that their customers infringe the '308 Patent.

74. Defendants have contributorily infringed and currently contributorily infringe the '308 Patent under 35 U.S.C. § 271(c). Defendants have designed the Accused Products specifically to be used in a manner as claimed in the '308 Patent. As such, the Accused Products

are a material component of the patented combinations, specifically designed to be used according to the claims of the '308 Patent, and especially made and adapted for use in a manner that infringes the '308 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. On information and belief, Defendants have knowledge of the '308 Patent and are aware that the Accused Products are especially made to be used in a system that infringes the '308 Patent.

75. Defendants have infringed and continue to infringe the '308 Patent under 35 U.S.C. § 271(f) by supplying components of the patented inventions or causing components of the patented inventions to be supplied in or from the United States for assembly abroad. Incorporating by reference each of the paragraphs above and below, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '308 Patent, and especially made and adapted for use in a manner that infringes the '308 Patent. Furthermore, the Accused Products represent all or a substantial portion of the patented combinations.

76. Defendants' infringement has been willful and deliberate because, on information and belief, they have known of the '308 Patent since at least September 2017 or September 2018, and knew or should have known of their infringement but acted despite an objectively high likelihood that such acts would infringe the '308 Patent.

77. As the direct and proximate result of Defendants' conduct, Plaintiffs have suffered, and if Defendants' conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs'

businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 2
(INFRINGEMENT OF THE '069 PATENT)

78. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

79. On information and belief, Defendants directly or through the actions of their employees, agents, distributors, divisions, and/or subsidiaries, have infringed and continue to infringe, one or more of the claims of the '069 Patent, including at least claim 1, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or supplying and/or importing the Accused Products throughout and from the United States, and/or inducing or contributing to such acts, without authority.

80. For example, the Accused Products and uses of the Accused Products meet each element of, and infringe, claim 1, which states:

> **Claim 1.** A method of amplifying a nucleic acid-containing sample within a microfluidic device, the method comprising:
> moving the sample from an upstream channel of the microfluidic device into a DNA manipulation module located downstream of the upstream channel, the DNA manipulation module including a DNA manipulation zone configured to perform amplification of the sample, a first valve disposed upstream of the DNA manipulation zone, and a second valve disposed downstream of the DNA manipulation zone, the only ingress to and egress from the DNA manipulation zone being through the first valve and the second valve;
> receiving the sample in the DNA manipulation zone;
> closing the first valve and the second valve such that gas and liquid are prevented from flowing into or out of the DNA manipulation zone; and
> thermal cycling the sample in the DNA manipulation zone.

81. Defendants infringe each element of claim 1 of the '069 Patent. Defendants' own documents, publicly posted videos, and patents that are marked on NeuMoDx products show that the Accused Products infringe the claims of the '069 Patent. As an example, U.S. Patent No. 8,703,069 Preliminary and Exemplary Claim Chart, detailing Defendants' infringement of these claims of the '069 Patent, is attached as **Exhibit 35**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of Defendants infringe the identified claims or any other claims of the '069 Patent or any other patents. **Exhibit 35** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 35** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

82. Defendants have also induced and currently induce infringement of the '069 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, Defendants know infringes the '069 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, NeuMoDx has known of the '069 Patent and of its infringement since at least September 2017, and QIAGEN has known of the '069 Patent and of its infringement since at least September 2018. By providing their customers with the Accused Products and those instructions for use, Defendants specifically intend that their customers infringe the '069 Patent.

83. Defendants have contributorily infringed and currently contributorily infringe the '069 Patent under 35 U.S.C. § 271(c). Defendants have designed the Accused Products specifically to be used in a manner as claimed in the '069 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according

to the claims of the '069 Patent, and especially made and adapted for use in a manner that infringes the '069 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. On information and belief, Defendants have knowledge of the '069 Patent and are aware that the Accused Products are especially made to be used in a system that infringes the '069 Patent.

84. Defendants have infringed and continue to infringe the '069 Patent under 35 U.S.C. § 271(f) by supplying components of the patented inventions or causing components of the patented inventions to be supplied in or from the United States for assembly abroad. Incorporating by reference each of the paragraphs above and below, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '069 Patent, and especially made and adapted for use in a manner that infringes the '069 Patent. Furthermore, the Accused Products represent all or a substantial portion of the patented combinations.

85. Defendants' infringement has been willful and deliberate because, on information and belief, they have known of the '069 Patent since at least September 2017 or September 2018, and knew or should have known of their infringement but acted despite an objectively high likelihood that such acts would infringe the '069 Patent.

86. As the direct and proximate result of Defendants' conduct, Plaintiffs have suffered, and if Defendants' conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 3
(INFRINGEMENT OF THE '708 PATENT)

87. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

88. On information and belief, Defendants directly or through the actions of their employees, agents, distributors, divisions, and/or subsidiaries, have infringed and continue to infringe, one or more of the claims of the '708 Patent, including at least claims 1 and 33, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or supplying and/or importing the Accused Products throughout and from the United States, and/or inducing or contributing to such acts, without authority.

89. For example, the Accused Products meet each element of, and infringe, claim 1, which states:

Claim 1. An apparatus, comprising:
a multi-lane microfluidic cartridge, each lane comprising a PCR reaction zone;
a receiving bay configured to receive the microfluidic cartridge;
each PCR reaction zone comprising a separately controllable heat source thermally coupled thereto, wherein the heat source maintains a substantially uniform temperature throughout the PCR reaction zone and thermal cycles the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone;
a detector configured to detect the presence of an amplification product in the respective PCR reaction zone; and
a processor coupled to the detector and the heat source, configured to control heating of one or more PCR reaction zones by the heat sources.

90. The Accused Products and uses of the Accused Products also meet each element of, and infringe, claim 33, which states:

Claim 33. A method of carrying out PCR on a plurality of samples, the method comprising:

introducing the plurality of samples into a multi-lane microfluidic cartridge, wherein each lane comprises a PCR reaction zone configured to permit thermal cycling of a sample independently of the other samples;
moving the plurality of samples into the respective plurality of PCR reaction zones; and
amplifying polynucleotides contained with the plurality of samples in the PCR reaction zones while thermal cycling the PCR reaction zones, at least one PCR reaction zone separately thermally controllable from another PCR reaction zone.

91. Defendants infringe each element of claims 1 and 33 of the '708 Patent. Defendants' own documents, publicly posted videos, and patents that are marked on NeuMoDx products show that the Accused Products infringe the claims of the '708 Patent. As an example, U.S. Patent No. 7,998,708 Preliminary and Exemplary Claim Chart, detailing Defendants' infringement of these claims of the '708 Patent, is attached as **Exhibit 36**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of Defendants infringe the identified claims or any other claims of the '708 Patent or any other patents. **Exhibit 36** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 36** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

92. Defendants have also induced and currently induce infringement of the '708 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, Defendants know infringes the '708 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, NeuMoDx has known of the '708 Patent and of its infringement since at least September 2017, and QIAGEN has known of the '708 Patent and of its infringement since at least September 2018. By providing their customers with the Accused Products and those instructions for use, Defendants specifically intend that their customers infringe the '708 Patent.

93. Defendants have contributorily infringed and currently contributorily infringe the '708 Patent under 35 U.S.C. § 271(c). Defendants have designed the Accused Products specifically to be used in a manner as claimed in the '708 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '708 Patent, and especially made and adapted for use in a manner that infringes the '708 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. On information and belief, Defendants have knowledge of the '708 Patent and are aware that the Accused Products are especially made to be used in a system that infringes the '708 Patent.

94. Defendants have infringed and continue to infringe the '708 Patent under 35 U.S.C. § 271(f) by supplying components of the patented inventions or causing components of the patented inventions to be supplied in or from the United States for assembly abroad. Incorporating by reference each of the paragraphs above and below, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '708 Patent, and especially made and adapted for use in a manner that infringes the '708 Patent. Furthermore, the Accused Products represent all or a substantial portion of the patented combinations.

95. Defendants' infringement has been willful and deliberate because, on information and belief, they have known of the '708 Patent and of their infringement since at least September 2017 or September 2018, and knew or should have known of their infringement but acted despite an objectively high likelihood that such acts would infringe the '708 Patent.

96. As the direct and proximate result of Defendants' conduct, Plaintiffs have suffered, and if Defendants' conduct is not enjoined, will continue to suffer, severe competitive harm,

irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 4
(INFRINGEMENT OF THE '900 PATENT)

97. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

98. On information and belief, Defendants directly or through the actions of their employees, agents, distributors, divisions, and/or subsidiaries, have infringed and continue to infringe, one or more of the claims of the '900 Patent, including at least claims 1, 7, and 20, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or supplying and/or importing the Accused Products throughout and from the United States, and/or inducing or contributing to such acts, without authority.

99. For example, the Accused Products meet each element of, and infringe, claim 1, which states:

> **Claim 1.** An apparatus, comprising:
> a plurality of multi-lane microfluidic cartridges, each lane comprising a PCR reaction zone;
> a plurality of receiving bays, each receiving bay configured to receive one of the plurality of microfluidic cartridges;
> each PCR reaction zone comprising a separately controllable heat source thermally coupled thereto, wherein the heat source thermal cycles the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone and maintains a substantially uniform temperature throughout the PCR reaction zone during each cycle;

a detector configured to detect the presence of an amplification product in one or more PCR reaction zones; and

a processor coupled to the detector and the heat sources, configured to control heating of one or more PCR reaction zones by the heat sources.

100. The Accused Products also meet each element of, and infringe, claim 7, which states:

Claim 7. A device for carrying out PCR on a plurality of samples, the device comprising:

a plurality of multi-lane microfluidic cartridges, each lane comprising a PCR reaction zone;

a plurality of receiving bays, each receiving bay configured to receive one of the plurality of microfluidic cartridges;

a separately controllable heat source thermally coupled to each PCR reaction zone, wherein the heat source is configured to thermal cycle the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone and to maintain a substantially uniform temperature throughout the PCR reaction zone during each cycle;

a detector configured to detect the presence of an amplification product in one or more PCR reaction zones;

a processor coupled to the detector and a plurality of the separately controllable heat sources, configured to control heating of one or more PCR reaction zones by one or more of the plurality of separately controllable heat sources; and

an input device coupled to the processor and configured to permit concurrent or consecutive control of the plurality of multi-lane microfluidic cartridges.

101. The Accused Products and uses of the Accused Products also meet each element of, and infringe, claim 20, which states:

Claim 20. A method of carrying out PCR on a plurality of samples, the method comprising:

introducing the plurality of samples into a plurality of multi-lane microfluidic cartridges, wherein each lane comprises a PCR reaction zone configured to permit thermal cycling of a sample independently of the other samples;

moving the plurality of samples into the respective plurality of PCR reaction zones; and

amplifying polynucleotides contained with the plurality of samples in the plurality of PCR reaction zones while thermal cycling the PCR reaction zones and maintaining a substantially uniform temperature throughout each PCR reaction zone during each cycle, at least one PCR reaction zone separately thermally controllable from another PCR reaction zone.

102. Defendants infringe each element of claims 1, 7, and 20 of the ’900 Patent. Defendants’ own documents, publicly posted videos, and patents that are marked on NeuMoDx

products show that the Accused Products infringe the claims of the '900 Patent. As an example, U.S. Patent No. 8,323,900 Preliminary and Exemplary Claim Chart, detailing Defendants' infringement of these claims of the '900 Patent, is attached as **Exhibit 37**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of Defendants infringe the identified claims or any other claims of the '900 Patent or any other patents. **Exhibit 37** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 37** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

103. Defendants have also induced and currently induce infringement of the '900 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, Defendants know infringes the '900 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, NeuMoDx has known of the '900 Patent and of its infringement since at least September 2017, and QIAGEN has known of the '900 Patent and of its infringement since at least September 2018. By providing their customers with the Accused Products and those instructions for use, Defendants specifically intend that their customers infringe the '900 Patent.

104. Defendants have contributorily infringed and currently contributorily infringe the '900 Patent under 35 U.S.C. § 271(c). Defendants have designed the Accused Products specifically to be used in a manner as claimed in the '900 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '900 Patent, and especially made and adapted for use in a manner that infringes the '900 Patent. The Accused Products are not staple articles of commerce and they do not have

substantial uses that do not infringe the Asserted Patents. On information and belief, Defendants have knowledge of the '900 Patent and are aware that the Accused Products are especially made to be used in a system that infringes the '900 Patent.

105. Defendants have infringed and continue to infringe the '900 Patent under 35 U.S.C. § 271(f) by supplying components of the patented inventions or causing components of the patented inventions to be supplied in or from the United States for assembly abroad. Incorporating by reference each of the paragraphs above and below, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '900 Patent, and especially made and adapted for use in a manner that infringes the '900 Patent. Furthermore, the Accused Products represent all or a substantial portion of the patented combinations.

106. Defendants' infringement has been willful and deliberate because, on information and belief, they have known of the '900 Patent and of their infringement since at least September 2017 or September 2018, and knew or should have known of their infringement but acted despite an objectively high likelihood that such acts would infringe the '900 Patent.

107. As the direct and proximate result of Defendants' conduct, Plaintiffs have suffered, and if Defendants' conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 5
(INFRINGEMENT OF THE '103 PATENT)

108. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

109. On information and belief, Defendants directly or through the actions of their employees, agents, distributors, divisions, and/or subsidiaries, have infringed and continue to infringe, one or more of the claims of the '103 Patent, including at least claims 1 and 15, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or supplying and/or importing the Accused Products throughout and from the United States, and/or inducing or contributing to such acts, without authority.

110. For example, the Accused Products and uses of the Accused Products meet each element of, and infringe, claim 1, which states:

> **Claim 1.** A method of carrying out amplification independently on a plurality of polynucleotide-containing samples, the method comprising:
> introducing the plurality of samples separately into a microfluidic cartridge;
> isolating the samples in the microfluidic cartridge;
> placing the microfluidic cartridge in thermal communication with an array of independent heaters; and
> amplifying polynucleotides in the plurality of samples by independent application of successive temperature cycles to each sample.

111. The Accused Products and uses of the Accused Products also meet each element of, and infringe, claim 15, which states:

> **Claim 15.** A method of carrying out amplification independently on a plurality of polynucleotide-containing samples, the method comprising:
> introducing the plurality of samples in to a microfluidic cartridge, wherein the cartridge has a plurality of reaction chambers configured to permit thermal cycling of the plurality of samples independently of one another;
> moving the plurality of samples independently of one another into the respective plurality of reaction chambers;

isolating the samples within the plurality of reaction chambers;
placing the microfluidic cartridge in thermal communication with an array of independent heaters; and
amplifying polynucleotides contained within the plurality of samples, by application of successive temperature cycles independently to the reaction chambers.

112. Defendants infringe each element of claims 1 and 15 of the '103 Patent. Defendants' own documents, publicly posted videos, and patents that are marked on NeuMoDx products show that the Accused Products infringe the claims of the '103 Patent. As an example, U.S. Patent No. 8,415,103 Preliminary and Exemplary Claim Chart, detailing Defendants' infringement of these claims of the '103 Patent, is attached as **Exhibit 38**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of Defendants infringe the identified claims or any other claims of the '103 Patent or any other patents. **Exhibit 38** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 38** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

113. Defendants have also induced and currently induce infringement of the '103 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, Defendants know infringes the '103 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, NeuMoDx has known of the '103 Patent and of its infringement since at least September 2017, and QIAGEN has known of the '103 Patent and of its infringement since at least September 2018. By providing their customers with the Accused Products and those instructions for use, Defendants specifically intend that their customers infringe the '103 Patent.

114. Defendants have contributorily infringed and currently contributorily infringe the '103 Patent under 35 U.S.C. § 271(c). Defendants have designed the Accused Products specifically to be used in a manner as claimed in the '103 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '103 Patent, and especially made and adapted for use in a manner that infringes the '103 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. On information and belief, Defendants have knowledge of the '103 Patent and are aware that the Accused Products are especially made to be used in a system that infringes the '103 Patent.

115. Defendants have infringed and continue to infringe the '103 Patent under 35 U.S.C. § 271(f) by supplying components of the patented inventions or causing components of the patented inventions to be supplied in or from the United States for assembly abroad. Incorporating by reference each of the paragraphs above and below, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '103 Patent, and especially made and adapted for use in a manner that infringes the '103 Patent. Furthermore, the Accused Products represent all or a substantial portion of the patented combinations.

116. Defendants' infringement has been willful and deliberate because, on information and belief, they have known of the '103 Patent and of their infringement since at least September 2017 or September 2018, and knew or should have known of their infringement but acted despite an objectively high likelihood that such acts would infringe the '103 Patent.

117. As the direct and proximate result of Defendants' conduct, Plaintiffs have suffered, and if Defendants' conduct is not enjoined, will continue to suffer, severe competitive harm,

irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 6
(INFRINGEMENT OF THE '787 PATENT)

118. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

119. On information and belief, Defendants directly or through the actions of their employees, agents, distributors, divisions, and/or subsidiaries, have infringed and continue to infringe, one or more of the claims of the '787 Patent, including at least claim 10, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or supplying and/or importing the Accused Products throughout and from the United States, and/or inducing or contributing to such acts, without authority.

120. For example, the Accused Products meet each element of, and infringe, claim 10, which states:

> **Claim 10.** A microfluidic substrate, comprising:
>
> a plurality of sample lanes, wherein each of the plurality of sample lanes comprises a microfluidic network having, in fluid communication with one another:
>
> an inlet;
>
> a first valve and a second valve;
>
> a first channel leading from the inlet, via the first valve, to a reaction chamber; and
>
> a second channel leading from the reaction chamber, via the second valve, to a vent,
>
> wherein the first valve and the second valve are configured to isolate the reaction chamber from the inlet and the vent to prevent movement of fluid into or

> out of the reaction chamber, wherein the first valve is spatially separated from the inlet and the second valve is spatially separated from the vent, wherein the reaction chamber, the first channel, and the second channel are formed in a first side of the microfluidic substrate, wherein the inlet and the vent are formed in a second side of the microfluidic substrate opposite the first side, and wherein the first valve in each of the plurality of sample lanes is operated independently of any other first valve.

121. Defendants infringe each element of claim 10 of the '787 Patent. Defendants' own documents, publicly posted videos, and patents that are marked on NeuMoDx products show that the Accused Products infringe the claims of the '787 Patent. As an example, U.S. Patent No. 8,709,787 Preliminary and Exemplary Claim Chart, detailing Defendants' infringement of these claims of the '787 Patent, is attached as **Exhibit 39**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of Defendants infringe the identified claims or any other claims of the '787 Patent or any other patents. **Exhibit 39** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 39** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

122. Defendants have also induced and currently induce infringement of the '787 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, Defendants know infringes the '787 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, NeuMoDx has known of the '787 Patent and of its infringement since at least September 2017, and QIAGEN has known of the '787 Patent and of its infringement since at least September 2018. By providing their customers with the Accused Products and those instructions for use, Defendants specifically intend that their customers infringe the '787 Patent.

123. Defendants have contributorily infringed and currently contributorily infringe the '787 Patent under 35 U.S.C. § 271(c). Defendants have designed the Accused Products specifically to be used in a manner as claimed in the '787 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '787 Patent, and especially made and adapted for use in a manner that infringes the '787 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. On information and belief, Defendants have knowledge of the '787 Patent and are aware that the Accused Products are especially made to be used in a system that infringes the '787 Patent.

124. Defendants have infringed and continue to infringe the '787 Patent under 35 U.S.C. § 271(f) by supplying components of the patented inventions or causing components of the patented inventions to be supplied in or from the United States for assembly abroad. Incorporating by reference each of the paragraphs above and below, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '787 Patent, and especially made and adapted for use in a manner that infringes the '787 Patent. Furthermore, the Accused Products represent all or a substantial portion of the patented combinations.

125. Defendants' infringement has been willful and deliberate because, on information and belief, they have known of the '787 Patent and of their infringement since at least September 2017 or September 2018, and knew or should have known of their infringement but acted despite an objectively high likelihood that such acts would infringe the '787 Patent.

126. As the direct and proximate result of Defendants' conduct, Plaintiffs have suffered, and if Defendants' conduct is not enjoined, will continue to suffer, severe competitive harm,

irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 7
(INFRINGEMENT OF THE '663 PATENT)

127. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

128. On information and belief, Defendants directly or through the actions of their employees, agents, distributors, divisions, and/or subsidiaries, have infringed and continue to infringe, one or more of the claims of the '663 Patent, including at least claim 1, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or supplying and/or importing the Accused Products throughout and from the United States, and/or inducing or contributing to such acts, without authority.

129. For example, the Accused Products meet each element of, and infringe, claim 1, which states:

> **Claim 1.** A method of isolating polynucleotides from a biological sample in a molecular diagnostic system, the method comprising:
> receiving the biological sample in a lysing container in the system;
> contacting the biological sample with a buffer solution and a lysing reagent in the lysing container, wherein the buffer solution has a pH of about 8.5 or less;
> heating the biological sample in the lysing container to a first temperature between about 30˚ C and about 50˚ C, wherein the polynucleotides are extracted from the biological sample into a lysate solution;
> contacting the polynucleotides with a plurality of magnetic binding particles in the lysing container, the plurality of magnetic binding particles

comprising polycationic molecules on the surface thereof, wherein at least a portion of the polynucleotides are retained on the plurality of magnetic binding particles in the lysate solution;

transferring the lysate solution containing the plurality of magnetic binding particles into a first processing region, wherein the first processing region is within a microfluidic network in the system, and wherein the lysing container is located external to the microfluidic network;

capturing the plurality of magnetic binding particles in the first processing region, wherein excess lysate solution flows through the first processing region, into a waste chamber;

introducing a wash solution into the first processing region to remove unbound material not retained by the plurality of magnetic binding particles;

introducing a release solution into the first processing region, wherein the release solution has a pH of at least 10.5;

heating the first processing region to a second temperature greater than the first temperature, wherein at least a portion of the polynucleotides are eluted from the plurality of magnetic binding particles into an eluate solution; and

transferring the eluate solution containing polynucleotides to a second processing region in the system, wherein the eluate solution reconstitutes PCR reagents contained in the second processing region to form a PCR-ready solution.

130. Defendants infringe each element of claim 1 of the ’663 Patent. Defendants’ own documents, publicly posted videos, and patents that are marked on NeuMoDx products show that the Accused Products infringe the claims of the ’663 Patent. As an example, U.S. Patent No. 10,494,663 Preliminary and Exemplary Claim Chart, detailing Defendants’ infringement of claim 1 of the ’663 Patent, is attached as **Exhibit 89**. This chart is not intended to limit Plaintiffs’ right to modify the chart or allege that other activities of Defendants infringe the identified claim or any other claims of the ’663 Patent or any other patents. **Exhibit 89** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 89** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

131. Defendants have also induced and currently induce infringement of the '663 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, Defendants know infringes the '663 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, Defendants have known of the '663 Patent and of their infringement. By providing their customers with the Accused Products and those instructions for use, Defendants specifically intend that their customers infringe the '663 Patent.

132. Defendants have contributorily infringed and currently contributorily infringe the '663 Patent under 35 U.S.C. § 271(c). Defendants have designed the Accused Products specifically to be used in a manner as claimed in the '663 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '663 Patent, and especially made and adapted for use in a manner that infringes the '663 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. On information and belief, Defendants have knowledge of the '663 Patent and are aware that the Accused Products are especially made to be used in a system that infringes the '663 Patent.

133. Defendants have infringed and continue to infringe the '663 Patent under 35 U.S.C. § 271(f) by supplying components of the patented inventions or causing components of the patented inventions to be supplied in or from the United States for assembly abroad. Incorporating by reference each of the paragraphs above and below, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '663 Patent, and especially made and adapted for use in a manner that infringes the '663

Patent. Furthermore, the Accused Products represent all or a substantial portion of the patented combinations.

134. Defendants' infringement has been willful and deliberate because, on information and belief, Defendants have known of the '663 Patent and of their infringement and knew or should have known of their infringement but acted despite an objectively high likelihood that such acts would infringe the '663 Patent.

135. As the direct and proximate result of Defendants' conduct, Plaintiffs have suffered, and if Defendants' conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 8
(INFRINGEMENT OF THE '456 PATENT)

136. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

137. On information and belief, Defendants directly or through the actions of their employees, agents, distributors, divisions, and/or subsidiaries, have infringed and continue to infringe, one or more of the claims of the '456 Patent, including at least claim 1, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or supplying and/or importing the Accused Products throughout and from the United States, and/or inducing or contributing to such acts, without authority.

138. For example, the Accused Products meet each element of, and infringe, claim 1, which states:

> **Claim 1.** A method for processing polynucleotide-containing sample, the method comprising:
> retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set of conditions, wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of binding particles comprising a poly-cationic substance, wherein the sample has a volume from 0.5 microliters to 3 milliliters;
> wherein the first set of conditions includes a first pH of about 8.5 or less and a first temperature, wherein the first temperature is about 50˚ C;
> releasing the polynucleotide from the plurality of binding particles under a second set of conditions; and
> wherein the second set of conditions includes increasing the pH to a second pH by addition of a hydroxide solution and increasing the temperature to a second temperature, wherein the second temperature is between about 80˚ C and about 100˚ C.

139. Defendants infringe each element of claim 1 of the ’456 Patent. Defendants’ own documents, publicly posted videos, and patents that are marked on NeuMoDx products show that the Accused Products infringe the claims of the ’456 Patent. As an example, U.S. Patent No. 10,364,456 Preliminary and Exemplary Claim Chart, detailing Defendants’ infringement of claim 1 of the ’456 Patent, is attached as **Exhibit 86**. This chart is not intended to limit Plaintiffs’ right to modify the chart or allege that other activities of Defendants infringe the identified claim or any other claims of the ’456 Patent or any other patents. **Exhibit 86** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 86** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

140. Defendants have also induced and currently induce infringement of the ’456 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use,

that, when followed in an intended manner and in a normal mode of operation, Defendants know infringes the '456 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, Defendants have known of the '456 Patent and of their infringement. By providing their customers with the Accused Products and those instructions for use, Defendants specifically intend that their customers infringe the '456 Patent.

141. Defendants have contributorily infringed and currently contributorily infringe the '456 Patent under 35 U.S.C. § 271(c). Defendants have designed the Accused Products specifically to be used in a manner as claimed in the '456 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '456 Patent, and especially made and adapted for use in a manner that infringes the '456 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. On information and belief, Defendants have knowledge of the '456 Patent and are aware that the Accused Products are especially made to be used in a system that infringes the '456 Patent.

142. Defendants have infringed and continue to infringe the '456 Patent under 35 U.S.C. § 271(f) by supplying components of the patented inventions or causing components of the patented inventions to be supplied in or from the United States for assembly abroad. Incorporating by reference each of the paragraphs above and below, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '456 Patent, and especially made and adapted for use in a manner that infringes the '456 Patent. Furthermore, the Accused Products represent all or a substantial portion of the patented combinations.

143. Defendants' infringement has been willful and deliberate because, on information and belief, Defendants have known of the '456 Patent and of their infringement and knew or should have known of their infringement but acted despite an objectively high likelihood that such acts would infringe the '456 Patent.

144. As the direct and proximate result of Defendants' conduct, Plaintiffs have suffered, and if Defendants' conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 9
(INFRINGEMENT OF THE '088 PATENT)

145. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

146. On information and belief, Defendants directly or through the actions of their employees, agents, distributors, divisions, and/or subsidiaries, have infringed and continue to infringe, one or more of the claims of the '088 Patent, including at least claim 1, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or supplying and/or importing the Accused Products throughout and from the United States, and/or inducing or contributing to such acts, without authority.

147. For example, the Accused Products meet each element of, and infringe, claim 1, which states:

Claim 1. A method for processing a polynucleotide-containing sample, the method comprising:

retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set of conditions, wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of binding particles comprising a poly-cationic substance, wherein the sample has a volume from 0.5 microliters to 3 milliliters;

wherein the first set of conditions includes a first pH of about 8.5 or less and a first temperature, wherein the first temperature is between about 30˚ C and about 50˚ C;

releasing the polynucleotide from the plurality of binding particles under a second set of conditions; and

wherein the second set of conditions includes increasing the pH to a second pH by addition of a hydroxide solution and increasing the temperature to a second temperature, wherein the second temperature is between 80˚ C and about 100˚ C.

148. Defendants infringe each element of claim 1 of the ’088 Patent. Defendants’ own documents, publicly posted videos, and patents that are marked on NeuMoDx products show that the Accused Products infringe the claims of the ’088 Patent. As an example, U.S. Patent No. 10,443,088 Preliminary and Exemplary Claim Chart, detailing Defendants’ infringement of claim 1 of the ’088 Patent, is attached as **Exhibit 87**. This chart is not intended to limit Plaintiffs’ right to modify the chart or allege that other activities of Defendants infringe the identified claim or any other claims of the ’088 Patent or any other patents. **Exhibit 87** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 87** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

149. Defendants have also induced and currently induce infringement of the ’088 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, Defendants know infringes the ’088 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-

ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, Defendants have known of the '088 Patent and of their infringement. By providing their customers with the Accused Products and those instructions for use, Defendants specifically intend that their customers infringe the '088 Patent.

150. Defendants have contributorily infringed and currently contributorily infringe the '088 Patent under 35 U.S.C. § 271(c). Defendants have designed the Accused Products specifically to be used in a manner as claimed in the '088 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '088 Patent, and especially made and adapted for use in a manner that infringes the '088 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. On information and belief, Defendants have knowledge of the '088 Patent and are aware that the Accused Products are especially made to be used in a system that infringes the '088 Patent.

151. Defendants have infringed and continue to infringe the '088 Patent under 35 U.S.C. § 271(f) by supplying components of the patented inventions or causing components of the patented inventions to be supplied in or from the United States for assembly abroad. Incorporating by reference each of the paragraphs above and below, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '088 Patent, and especially made and adapted for use in a manner that infringes the '088 Patent. Furthermore, the Accused Products represent all or a substantial portion of the patented combinations.

152. Defendants' infringement has been willful and deliberate because, on information and belief, Defendants have known of the '088 Patent and of their infringement and knew or should

have known of their infringement but acted despite an objectively high likelihood that such acts would infringe the '088 Patent.

153. As the direct and proximate result of Defendants' conduct, Plaintiffs have suffered, and if Defendants' conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 10
(INFRINGEMENT OF THE '788 PATENT)

154. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

155. On information and belief, Defendants directly or through the actions of their employees, agents, distributors, divisions, and/or subsidiaries, have infringed and continue to infringe, one or more of the claims of the '788 Patent, including at least claim 1, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or supplying and/or importing the Accused Products throughout and from the United States, and/or inducing or contributing to such acts, without authority.

156. For example, the Accused Products meet each element of, and infringe, claim 1, which states:

> **Claim 1.** A system for processing polynucleotides in a biological sample, the system comprising:

a microfluidic device comprising substrate layers that define a microfluidic network, the microfluidic network comprising a first processing region, the microfluidic device further comprising a waste chamber downstream of the first processing region;

a lysing container located external to the substrate layers, wherein the lysing container is configured to receive the biological sample and configured to place the biological sample in contact with a lysing reagent to release polynucleotides from the biological sample into a lysate solution;

a plurality of magnetic binding particles disposed in the lysing container, the plurality of magnetic binding particles comprising polycationic molecules on the surfaces thereof, wherein the plurality of magnetic binding particles are configured to retain at least a portion of the polynucleotides on the surface thereof in the lysate solution at a pH of 8.5 or less;

a first heat source and a second heat source located external to the microfluidic network;

a lysing heater configured to apply heat to the lysate solution and the plurality of magnetic binding particles in the lysing container, wherein the lysing heater is separate and distinct from the first and second heat sources;

an operating system comprising a processor, the processor configured to actuate the first and second heat sources and the lysing heater;

wherein the operating system is configured to actuate the lysing heater to heat the lysate solution in the lysing container to a first temperature;

wherein the first processing region of the microfluidic network is configured to receive the lysate solution and the plurality of magnetic binding particles from the lysing container, wherein the waste chamber is configured to receive excess lysate solution downstream of the first processing region as the plurality of magnetic binding particles are retained in the first processing region;

wherein the microfluidic network is configured to receive a wash solution in the first processing region to remove unbound material not retained by the plurality of magnetic binding particles;

a release solution having a pH of at least 11.4;

wherein the microfluidic network further comprises an inlet for receiving the release solution into the microfluidic network and one or more channels leading from the inlet to the first processing region;

wherein the first processing region is configured to receive the release solution therein, and wherein, in the presence of the release solution in the first processing region, the plurality of magnetic binding particles are configured to release at least a portion of the polynucleotides into an eluate solution in the first processing region;

wherein the first heat source is configured to apply heat to the lysate solution and the plurality of magnetic binding particles in the first processing region, and wherein the operating system is configured to actuate the first heat source to heat the lysate solution in the first processing region to a second temperature greater than the first temperature; and

a second processing region comprising PCR reagents, the second processing region configured to receive the eluate solution containing polynucleotides and configured to place the eluate solution in contact with PCR reagents to form a PCR-ready solution.

157. Defendants infringe each element of claim 1 of the '788 Patent. Defendants' own documents, publicly posted videos, and patents that are marked on NeuMoDx products show that the Accused Products infringe the claims of the '788 Patent. As an example, U.S. Patent No. 10,604,788 Preliminary and Exemplary Claim Chart, detailing Defendants' infringement of claim 1 of the '788 Patent, is attached as **Exhibit 88**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of Defendants infringe the identified claim or any other claims of the '788 Patent or any other patents. **Exhibit 88** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 88** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

158. Defendants have also induced and currently induce infringement of the '788 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, Defendants know infringes the '788 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-

ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, Defendants have known of the '788 Patent and of their infringement. By providing its customers with the Accused Products and those instructions for use, Defendants specifically intend that their customers infringe the '788 Patent.

159. Defendants have contributorily infringed and currently contributorily infringe the '788 Patent under 35 U.S.C. § 271(c). Defendants have designed the Accused Products specifically to be used in a manner as claimed in the '788 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '788 Patent, and especially made and adapted for use in a manner that infringes the '788 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. On information and belief, Defendants have knowledge of the '788 Patent and are aware that the Accused Products are especially made to be used in a system that infringes the '788 Patent.

160. Defendants have infringed and continue to infringe the '788 Patent under 35 U.S.C. § 271(f) by supplying components of the patented inventions or causing components of the patented inventions to be supplied in or from the United States for assembly abroad. Incorporating by reference each of the paragraphs above and below, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '788 Patent, and especially made and adapted for use in a manner that infringes the '788 Patent. Furthermore, the Accused Products represent all or a substantial portion of the patented combinations.

161. Defendants' infringement has been willful and deliberate because, on information and belief, Defendants have known of the '788 Patent and of their infringement and knew or

should have known of their infringement but acted despite an objectively high likelihood that such acts would infringe the '788 Patent.

162. As the direct and proximate result of Defendants' conduct, Plaintiffs have suffered, and if Defendants' conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 11
(INFRINGEMENT OF THE '261 PATENT)

163. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

164. On information and belief, Defendants directly or through the actions of their employees, agents, distributors, divisions, and/or subsidiaries, have infringed and continue to infringe, one or more of the claims of the '261 Patent, including at least claim 1, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or supplying and/or importing the Accused Products throughout and from the United States, and/or inducing or contributing to such acts, without authority.

165. The Accused Products and uses of the Accused Products also meet each element of, and infringe, claim 1, which states:

> **Claim 1.** A system for processing a plurality of nucleic acid-containing samples, the system comprising:

a first module configured to extract nucleic acids from the plurality of nucleic acid-containing samples,

a second module configured to amplify the nucleic acid extracted from the plurality of nucleic acid-containing samples, the first and second modules comprising:

a bay configured to removably receive a housing comprising a plurality of process chambers that are maintained at a same height relative to one another when the housing is received in the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members configured to receive the housing in a single orientation when the housing is received in the bay,

the first module further comprising a magnetic separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, and

the first module further comprising a heating assembly positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay, the heater assembly comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay, the heating assembly configured to heat a solution in the plurality of process chambers to between 50˚ C and 85˚ C, the one or more complementary registration members configured to align the plurality of process chambers with the heater assembly when the housing is received in the bay; and

a liquid dispenser configured to move between a first location and a second location when the housing is received in the bay, the liquid dispenser configured to dispense at least a portion of the plurality of nucleic acid-containing samples and a plurality of magnetic binding particles when the housing is received in the bay and the liquid dispenser is in the first location, the liquid dispenser further configured to dispense the nucleic acid extracted from the plurality of nucleic-acid containing samples when the liquid dispenser is in the second location.

166. Defendants infringe each element of claim 1 of the ’261 Patent. Defendants’ own documents, publicly posted videos, and patents that are marked on NeuMoDx products show that the Accused Products infringe the claims of the ’261 Patent. As an example, U.S. Patent No.

10,625,261 Preliminary and Exemplary Claim Chart, detailing Defendants' infringement of claim 1 of the '261 Patent, is attached as **Exhibit 90**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of Defendants infringe the identified claim or any other claims of the '261 Patent or any other patents. **Exhibit 90** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 90** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

167. Defendants have also induced and currently induce infringement of the '261 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, Defendants know infringes the '261 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, Defendants have known of the '261 Patent and of their infringement. By providing their customers with the Accused Products and those instructions for use, Defendants specifically intend that their customers infringe the '261 Patent.

168. Defendants have contributorily infringed and currently contributorily infringe the '261 Patent under 35 U.S.C. § 271(c). Defendants have designed the Accused Products specifically to be used in a manner as claimed in the '261 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '261 Patent, and especially made and adapted for use in a manner that infringes the '261 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. On information and belief, Defendants

have knowledge of the '261 Patent and are aware that the Accused Products are especially made to be used in a system that infringes the '261 Patent.

169. Defendants have infringed and continue to infringe the '261 Patent under 35 U.S.C. § 271(f) by supplying components of the patented inventions or causing components of the patented inventions to be supplied in or from the United States for assembly abroad. Incorporating by reference each of the paragraphs above and below, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '261 Patent, and especially made and adapted for use in a manner that infringes the '261 Patent. Furthermore, the Accused Products represent all or a substantial portion of the patented combinations.

170. Defendants' infringement has been willful and deliberate because, on information and belief, Defendants have known of the '261 Patent and of their infringement and knew or should have known of their infringement but acted despite an objectively high likelihood that such acts would infringe the '261 Patent.

171. As the direct and proximate result of Defendants' conduct, Plaintiffs have suffered, and if Defendants' conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 12
(INFRINGEMENT OF THE '262 PATENT)

172. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

173. On information and belief, Defendants directly or through the actions of their employees, agents, distributors, divisions, and/or subsidiaries, have infringed and continue to infringe, one or more of the claims of the '262 Patent, including at least claim 1, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or supplying and/or importing the Accused Products throughout and from the United States, and/or inducing or contributing to such acts, without authority.

174. The Accused Products and uses of the Accused Products also meet each element of, and infringe, claim 1, which states:

> **Claim 1.** A system for processing a plurality of nucleic acid-containing samples, the system comprising:
>
> a first module configured to extract nucleic acids from the plurality of nucleic acid-containing samples, the first module comprising:
>
> a plurality of sample tubes in the first module, each sample tube configured to accept a nucleic acid-containing sample of the plurality of nucleic-acid containing samples,
>
> a plurality of process chambers in the first module, wherein a process chamber of the plurality of process chambers is spatially separate from, and corresponds to, a sample tube of the plurality of sample tubes, the plurality of process chambers maintained at a same height relative to one another in the first module,
>
> a waste chamber in the first module, the waste chamber corresponding to a process chamber of the plurality of process chambers in the first module,
>
> a magnetic separator configured to apply a magnetic force to at least one process chamber of the plurality of process chambers in the first module;
>
> a heater assembly configured to heat at least one process chamber of the plurality of process chambers in the first module;
>
> a second module configured to receive nucleic acids extracted from the plurality of nucleic acid-containing samples, the second module comprising:
>
> a plurality of receptacles comprising PCR reagents, wherein a receptacle of the plurality of receptacles is configured to receive

nucleic acid extracted from a sample of the plurality of nucleic acid-containing samples; and

a liquid dispenser configured to dispense or withdraw liquid from the plurality of sample tubes and dispense or withdraw liquid from the plurality of receptacles comprising PCR reagents.

175. Defendants infringe each element of claim 1 of the '262 Patent. Defendants' own documents, publicly posted videos, and patents that are marked on NeuMoDx products show that the Accused Products infringe the claims of the '262 Patent. As an example, U.S. Patent No. 10,625,262 Preliminary and Exemplary Claim Chart, detailing Defendants' infringement of claim 1 of the '262 Patent, is attached as **Exhibit 91**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of Defendants infringe the identified claim or any other claims of the '262 Patent or any other patents. **Exhibit 91** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 91** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

176. Defendants have also induced and currently induce infringement of the '262 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, Defendants know infringes the '262 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, Defendants have known of the '262 Patent and of their infringement. By providing their customers with the Accused Products and those instructions for use, Defendants specifically intend that their customers infringe the '262 Patent.

177. Defendants have contributorily infringed and currently contributorily infringe the '262 Patent under 35 U.S.C. § 271(c). Defendants have designed the Accused Products

specifically to be used in a manner as claimed in the '262 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '262 Patent, and especially made and adapted for use in a manner that infringes the '262 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. On information and belief, Defendants have knowledge of the '262 Patent and are aware that the Accused Products are especially made to be used in a system that infringes the '262 Patent.

178. Defendants have infringed and continue to infringe the '262 Patent under 35 U.S.C. § 271(f) by supplying components of the patented inventions or causing components of the patented inventions to be supplied in or from the United States for assembly abroad. Incorporating by reference each of the paragraphs above and below, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '262 Patent, and especially made and adapted for use in a manner that infringes the '262 Patent. Furthermore, the Accused Products represent all or a substantial portion of the patented combinations.

179. Defendants' infringement has been willful and deliberate because, on information and belief, Defendants' have known of the '262 Patent and of their infringement and knew or should have known of their infringement but acted despite an objectively high likelihood that such acts would infringe the '262 Patent.

180. As the direct and proximate result of Defendants' conduct, Plaintiffs have suffered, and if Defendants' conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs'

businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

COUNT 13
(INFRINGEMENT OF THE '466 PATENT)

181. Plaintiffs incorporate each of the paragraphs above and below as though fully set forth herein.

182. On information and belief, Defendants directly or through the actions of their employees, agents, distributors, divisions, and/or subsidiaries, have infringed and continue to infringe, one or more of the claims of the '466 Patent, including at least claim 1, directly, indirectly, literally and/or by equivalents under 35 U.S.C. *et seq.*, including, but not limited to § 271 by, among other things, making, using (including during research and development activities and product testing), selling, offering for sale the Accused Products in the United States and/or supplying and/or importing the Accused Products throughout and from the United States, and/or inducing or contributing to such acts, without authority.

183. The Accused Products and uses of the Accused Products also meet each element of, and infringe, claim 1, which states:

> **Claim 1.** A method of analyzing a plurality of nucleic acid-containing samples, the method comprising:
>
> extracting nucleic acids from the plurality of nucleic acid-containing samples in a first module and amplifying the nucleic acid extracted from the plurality of nucleic acid-containing samples simultaneously in a second module using a system comprising a liquid dispenser and a bay, the first module comprising a magnetic separator and a heating assembly, wherein extracting the nucleic acids comprises:
>
> removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more

complementary registration members that receive the housing in a single orientation when the housing is received in the bay, the magnetic separator of the first module positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic esparto comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the magnetic separator when the housing is received in the bay, the heating assembly of the first module positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay, the heater assembly comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the heater assembly when the housing is received in the bay;

moving the liquid dispenser between the plurality of nucleic acid-containing samples and the plurality of process chambers when the housing is received in the bay;

dispensing, using the liquid dispenser, at least a portion of the plurality of nucleic acid-containing samples and a plurality of magnetic binding particles into the plurality of process chambers when the housing is received in the bay;

applying a magnetic force to the first side of the plurality of process chambers using the one or more magnets of the magnetic separator of the first module when the housing is received in the bay;

holding the plurality of magnetic binding particles bound to nucleic acids of the plurality of nucleic acid-containing samples against walls of the plurality of process chambers using the magnetic separator of the first module;

moving, using the liquid dispenser, a portion of a solution contained in each of the plurality of process chambers to a waste chamber;

dispensing, using the liquid dispenser, a wash buffer into the plurality of process chambers;

dispensing, using the liquid dispenser, a release buffer into the plurality of process chambers and over the plurality of magnetic binding particles in the plurality of process chambers;

heating the release buffer in the plurality of process chambers to between about 50˚ C and about 85˚ C using the heater assembly of the first module;

using the liquid dispenser, withdrawing liquid containing extracted nucleic acid from the plurality of process chambers; and

dispensing the nucleic acid extracted from the plurality of nucleic-acid containing samples into the second module.

184. Defendants infringe each element of claim 1 of the '466 Patent. Defendants' own documents, publicly posted videos, and patents that are marked on NeuMoDx products show that the Accused Products infringe the claims of the '466 Patent. As an example, U.S. Patent No. 10,632,466 Preliminary and Exemplary Claim Chart, detailing Defendants' infringement of claim 1 of the '466 Patent, is attached as **Exhibit 92**. This chart is not intended to limit Plaintiffs' right to modify the chart or allege that other activities of Defendants infringe the identified claim or any other claims of the '466 Patent or any other patents. **Exhibit 92** is hereby incorporated by reference in its entirety. Each claim element in **Exhibit 92** that is mapped to the Accused Products shall be considered an allegation within the meaning of the Federal Rules of Civil Procedure and therefore a response to each allegation is required.

185. Defendants have also induced and currently induce infringement of the '466 Patent under § 271(b) by providing customers with the Accused Products, along with instructions for use, that, when followed in an intended manner and in a normal mode of operation, Defendants know infringes the '466 Patent. *See, e.g.*, **Exhibit 19**, 40600094_D-IFU-NeuMoDx-Cartridge-US-ONLY.pdf (providing instructions for using the NeuMoDx™ Cartridge, Product Code 100100). On information and belief, Defendant has known of the '466 Patent and of their infringement. By providing their customers with the Accused Products and those instructions for use, Defendants specifically intend that their customers infringe the '466 Patent.

186. Defendants have contributorily infringed and currently contributorily infringe the '466 Patent under 35 U.S.C. § 271(c). Defendants have designed the Accused Products specifically to be used in a manner as claimed in the '466 Patent. As such, the Accused Products are a material component of the patented combinations, specifically designed to be used according

to the claims of the '466 Patent, and especially made and adapted for use in a manner that infringes the '466 Patent. The Accused Products are not staple articles of commerce and they do not have substantial uses that do not infringe the Asserted Patents. On information and belief, Defendants have knowledge of the '466 Patent and are aware that the Accused Products are especially made to be used in a system that infringes the '466 Patent.

187. Defendants have infringed and continue to infringe the '466 Patent under 35 U.S.C. § 271(f) by supplying components of the patented inventions or causing components of the patented inventions to be supplied in or from the United States for assembly abroad. Incorporating by reference each of the paragraphs above and below, the Accused Products are a material component of the patented combinations, specifically designed to be used according to the claims of the '466 Patent, and especially made and adapted for use in a manner that infringes the '466 Patent. Furthermore, the Accused Products represent all or a substantial portion of the patented combinations.

188. Defendants' infringement has been willful and deliberate because, on information and belief, Defendants have known of the '466 Patent and of their infringement and knew or should have known of their infringement but acted despite an objectively high likelihood that such acts would infringe the '466 Patent.

189. As the direct and proximate result of Defendants' conduct, Plaintiffs have suffered, and if Defendants' conduct is not enjoined, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, injunctive relief. Plaintiffs' businesses operate in a competitive market and they will continue suffering irreparable harm absent injunctive relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief, declaration and judgment that:

a. Defendants have infringed the Asserted Patents;

b. Plaintiffs are entitled to preliminary and permanent injunctive relief enjoining Defendants, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering for sale, selling in the United States, or importing into the United States, the Accused Products, and any other product that infringes or induces or contributes to the infringement of the Asserted Patents, prior to the expiration date of the last to expire of those patents;

c. Plaintiffs are entitled to an award of damages pursuant to 35 U.S.C. § 284, including pre-judgment and post-judgment interest;

d. Defendants' infringement of the Asserted Patents has been willful and Plaintiffs are entitled to enhanced damages up to and including trebling of the damages awarded to it;

e. Plaintiffs are entitled to their costs and reasonable expenses to the fullest extent permitted by law;

f. This case is exceptional pursuant to 35 U.S.C. § 285, and Plaintiffs are entitled to an award of attorneys' fees; and

g. Plaintiffs are entitled to other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury on all issues so triable.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Michael J. Flynn

Jack B. Blumenfeld (#1014)
Michael J. Flynn (#5333)
Andrew M. Moshos (#6685)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mflynn@mnat.com
amoshos@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Amy K. Wigmore
Heather M. Petruzzi
David P. Yin
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
(202) 663-6000

Omar A. Khan
Barish Ozdamar
Laura Macro
WILMER CUTLER PICKERING HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

February 25, 2021

CERTIFICATE OF SERVICE

I hereby certify that on February 25, 2021, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on February 25, 2021, upon the following in the manner indicated:

Brian E. Farnan, Esquire — *VIA ELECTRONIC MAIL*
Michael J. Farnan, Esquire
FARNAN LLP
919 North Market Street, 12th Floor
Wilmington, DE 19801
Attorneys for Defendants

James K. Cleland, Esquire — *VIA ELECTRONIC MAIL*
DICKINSON WRIGHT PLLC
350 South Main Street, Suite 300
Ann Arbor, MI 48104
Attorneys for Defendants

Alan G. Carlson, Esquire — *VIA ELECTRONIC MAIL*
J. Derek Vandenburgh, Esquire
Gary J. Speier, Esquire
Jonathan D. Carpenter, Esquire
Peter M. Kohlhepp, Esquire
Samuel T. Lockner, Esquire
Alexandra J. Olson, Esquire
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.
225 South 6th Street, Suite 4200
Minneapolis, MN 55402
Attorneys for Defendants

/s/ Michael J. Flynn

Michael J. Flynn (#5333)